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COUNTY OF SANTA CLARA and THE
SANTA CLARA COUNTY
PUBLIC HEALTH DEPARTMENT

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CALIFORNIA RESTAURANT ASSOCIATION Plaintiff, v. THE COUNTY OF SANTA CLARA and THE SANTA CLARA COUNTY PUBLIC HEALTH DEPARTMENT Defendants.	No. C08-03685 CW **DECLARATION OF MIGUEL MÁRQUEZ IN OPPOSITION TO PLAINTIFF'S MOTION FOR DECLARATORY AND RELIEF AND PRELIMINARY INJUNCTION** Hearing Date: August 28, 2008 Time: 2:00 p.m. Dept.: Ctrm. 2, 4th Fl.

I, Miguel Márquez, declare as follows:

I am an Assistant County Counsel for the County of Santa Clara. I am a member in good standing of the bar of this Court. I have personal knowledge of the matters stated herein, except for those matters set forth on information and belief which I believe to be true and, if called to testify, I can and will testify competently as to all matters set forth herein.

1. Attached as Exhibit 1 is a true and correct copy of the order by the United States Court of Appeals for The Second Circuit, dated June 16, 2008, in the case entitled *New York City Restaurant Association v. New York City Board of Health, et al.*, 08-1892-cv.

2. Attached as Exhibit 2 is a true and correct copy of the "Brief Of The United States Food And Drug Administration As Amicus Curiae In Support of Affirmance," dated May

29, 2008, filed with the United States Court of Appeals for the Second Circuit, in the case of *New York City Restaurant Association v. New York City Board of Health, et al.*, 08-1892-cv.

3. Attached as Exhibit 3 is a true and correct copy of FDA, Food Labeling: Questions and Answers, Volume II, "A Guide for Restaurants and Other Retail Establishments," dated August 1995, *available at* http://vm.cfsan.fda.gov/~frf/qatext2.html.

4. Attached as Exhibit 4 is a true and correct copy of FDA, "Counting Calories: Report of the Working Group on Obesity," dated 2004, *available at* http://vm.cfsan.fda.gov/~dms/owg-rpt.html.

5. Attached as Exhibit 5 is a true and correct copy of FDA, "Guidance for Industry: A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods," dated April 2008, *available at* http://vm/cfsan.fda.gov/~dms/labrguid.html.

I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct to the best of my knowledge.

Executed on the 19th day of August, 2008, at San Jose, California.

MIGUEL MARQUEZ

ANN MILLER RAVEL
County Counsel
County of Santa Clara
San Jose, California

S.D.N.Y. - N.Y.C.
08-cv-1000
Holwell, J.

United States Court of Appeals
FOR THE
SECOND CIRCUIT

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 16th day of June, two thousand eight,

Present: Hon. Rosemary S. Pooler,
Hon. Sonia Sotomayor,
Circuit Judges,
Hon. Jane A. Restani,
Judge.

New York State Restaurant Association,

Plaintiff-Appellant,

v. 08-1892-cv

New York City Board of Health, *et al.*,

Defendants-Appellees.

Appellant, through counsel, moves for an order maintaining the *status quo* pending a decision on the merits of this appeal – i.e. the continuation of a stay for a "no fine" period beyond July 18, 2008. When Appellant initially moved for this order on June 6, 2008, we denied the motion without prejudice to renewal at or after oral argument. At oral argument on June 12, 2008, appellant renewed its motion. Upon due consideration, it is hereby ORDERED that the motion is DENIED.

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk

By: _____

08-1892-cv

United States Court of Appeals

FOR THE SECOND CIRCUIT

Docket No. 08-1892-cv

NEW YORK STATE RESTAURANT ASSOCIATION,

Plaintiff-Appellant,

(*Caption continued on inside cover*)

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION AS *AMICUS CURIAE* IN SUPPORT OF AFFIRMANCE

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—v.—

NEW YORK CITY BOARD OF HEALTH, NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, THOMAS R. FRIEDEN, In His Official Capacity as Commissioner of the New York City Department of Health and Mental Hygiene,

Defendants-Appellees.

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FOR THE SECOND CIRCUIT

Docket No. 08-1892-cv

NEW YORK STATE RESTAURANT ASSOCIATION,

Plaintiff-Appellant,

—v.—

NEW YORK CITY BOARD OF HEALTH, NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, THOMAS R. FRIEDEN, IN HIS OFFICIAL CAPACITY AS COMMISSIONER OF THE NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE ,

Defendants-Appellees.

BRIEF OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION AS *AMICUS CURIAE* IN SUPPORT OF AFFIRMANCE

Preliminary Statement

Pursuant to Rule 29(a) of the Federal Rules of Appellate Procedure and the request of the Court during the April 29, 2008 oral argument on appellant's motion for a stay pending appeal, the United States Food and Drug Administration ("FDA") respectfully submits this *amicus curiae* brief in support of affirmance of the district court's judgment.

For the reasons detailed below, New York City Health Code Regulation 81.50 is not expressly preempted by the Nutrition Labeling and Education Act of 1990, 21 U.S.C. §§ 343-1(a)(4), (5) (the "NLEA"). The NLEA expressly preempts any state "requirement for nutrition labeling of food that is not identical to the requirement of [section 343(q) of the Act], except a requirement for nutrition labeling of food which is exempt under [certain provisions of section 343(q)]." 21 U.S.C. § 343-1(a)(4). Because food served in restaurants is explicitly exempted from a specified provision of section 343(q), state and municipal authority to impose mandatory nutrition labeling on restaurants is necessarily preserved. The requirement in Regulation 81.50(c) that certain restaurants list the "total number of calories . . . for each menu item they list, . . . clearly and conspicuously, adjacent or in close proximity such as to be clearly associated with the menu item," does not require a "nutrient content claim," which would trigger express preemption. Rather, it compels the disclosure of "nutrition information," as that term is used in sections 343(q) and 343(r)(1), and accordingly is not expressly preempted under the NLEA.

In addition, Regulation 81.50 does not violate the First Amendment.* The Regulation implicates purely

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* While the Court specifically requested FDA's views concerning the statutory preemption issue, this brief also addresses the First Amendment issue, which the Court must reach if it finds Regulation 81.50 not preempted by federal law. The issue is of great importance to the FDA and other federal agencies, because, as the Court itself has recognized, there are

commercial speech, and thus is subject to less stringent constitutional requirements than other forms of speech. Because the Regulation compels an accurate, purely factual disclosure of the calorie content of restaurant menu items, and addresses a legitimate state interest in preventing or reducing obesity among its citizens by making accurate calorie information available to consumers, there is a rational connection between the disclosure requirement and the City's purpose in imposing it such that the Regulation survives constitutional analysis.

Issues Presented

1. Whether New York City Regulation 81.50, which requires national chain restaurants to post statements showing the number of calories for each item on their menus and menu boards, is expressly preempted by the Nutrition Labeling and Education Act of 1990, 21 U.S.C. § 343-1(a)(4) or (5).

2. Whether Regulation 81.50's requirement that restaurants provide a purely factual statement of the calorie content of their menu offerings impermissibly infringes on the First Amendment rights of the members of plaintiff-appellant New York State Restaurant Association ("NYSRA").

"[i]nnumerable federal and state regulatory programs" that "require the disclosure of product and other commercial information." *National Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 116 (2d Cir. 2001), *cert. denied*, 536 U.S. 905 (2002).

Statement of the Case

A. Federal Statutory Scheme Governing Food Labeling

The Federal Food, Drug, and Cosmetic Act (the "FDCA"), enacted in 1938, generally prohibits the misbranding of food. In 1990, Congress passed the Nutrition Labeling and Education Act (the "NLEA"), Pub.L. No. 101-535, 104 Stat. 2535 (1990), requiring nutrition labeling on most packaged foods and regulating certain claims concerning food. The House Report accompanying the bill described the dual purposes as follows: "[T]o clarify and to strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods." H.R.Rep. No. 101-538, at 7 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337.

The NLEA added two new sections to the Federal Food, Drug, and Cosmetic Act. *See* 21 U.S.C. §§ 343(q), (r). The first, 21 U.S.C. § 343(q), mandates specific, uniform disclosures that must be made on food labels, giving rise to the familiar "Nutrition Facts" panel on packaged foods that sets forth calories per serving, as well as the quantities of various nutrients, including fat, cholesterol, sodium, carbohydrates, protein, and select vitamins and minerals. The second provision, 21 U.S.C. § 343(r), gives the FDA broad authority to regulate when and how a food purveyor may make claims about the nutrient content or certain health benefits of its product.

The NLEA expressly exempts food "served in restaurants" from mandatory nutrition labeling. *See* 21 U.S.C.

§ 343(q)(5)(A)(i). By contrast, restaurants are not generally exempt from subsection (r) and are subject to FDA regulation if they make a nutrient content claim. *See* 21 C.F.R. § 101.13(q)(5) ("A nutrient content claim used on food that is served in restaurants . . . shall comply with the requirements of this section"). The difference between these two provisions is critical for this case. Subsection (r) applies to "a claim . . . made in the label or labeling of . . . food" that "expressly or by implication . . . characterizes the level of any nutrient." 21 U.S.C. § 343(r)(1)(A). Examples of such claims include "low sodium," "lite," or "high in oat bran." H.R. Rep. 101-538, at 19, 1990 U.S.C.C.A.N. at 3349. However, the statute provides that a "statement of the type required by paragraph (q) of this section that appears as part of the nutrition information required or permitted by such paragraph is not a claim." 21 U.S.C. § 343(r)(1).

B. Preemption Provisions in the NLEA

In enacting the NLEA, Congress added two express preemption provisions, 21 U.S.C. § 343-1(a)(4) and (a)(5), which address the scope of preemption for mandatory nutrition labeling requirements under § 343(q) and for nutrient content claim regulations under § 343(r).

Section 343-1(a)(4) expressly preempts any state or municipal "requirement for nutrition labeling of food that is not identical to the requirement of [§ 343(q)], except a requirement for nutrition labeling of food which is exempt under [certain provisions of § 343(q)]."

21 U.S.C. § 343-1(a)(4).* Because food served in restaurants is explicitly exempt from § 343(q) under a referenced provision, state or municipal authority to impose nutrition labeling requirements on restaurants is undisturbed by the NLEA.

Section 343-1(a)(5), on the other hand, expressly preempts states (or municipalities) from imposing any requirement on nutrient content claims made by a food purveyor "in the label or labeling of food that is not identical to the requirement of § 343(r)," "except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B)." 21 U.S.C. § 343-1(a)(5). Although § 343(r)(5)(B) exempts from express preemption some claims regarding "food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments," 21 U.S.C. § 343(r)(5)(B), this provision does not exempt claims regarding calories.

C. NLEA's Preservation of Other Statutes' Potentially Preclusive Effect

When enacting the NLEA, Congress provided that the statute "shall not be construed to preempt any provision of State law, unless such provision is ex-

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* Specifically, § 343-1(a)(4) exempts "food which is exempt under subclause (i) or (ii) of section 343(q)(5)(A) . . . ." Section 343(q)(5)(A)(i) applies to food "which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments."

pressly preempted under [§ 343-1] of the Federal Food, Drug, and Cosmetic Act." Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2535, 2364. However, Congress further provided that the NLEA should not be construed to affect express or implied preemption under other provisions of the Federal Food, Drug, and Cosmetic Act. *Id.* § 6(c)(3) ("The amendment made by subsection (a), the provisions of subsection (b) and paragraphs (1) and (2) of this subsection shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food, Drug, and Cosmetic Act not amended by subsection (a), any other Federal law, or any Federal regulation . . . ."). Thus, any state or local food labeling regulation, even if expressly exempted from preemption under the NLEA, that renders food labeling false or misleading would be impliedly preempted under 21 U.S.C. § 343(a) of the FDCA.

D. New York City's Initial Calorie Disclosure Regulation and Prior Litigation

In December 2006, the New York City Board of Health adopted a resolution amending Article 81 of the Health Code by adding a new § 81.50. The regulation was to become effective on July 1, 2007, and mandated that any food service establishment making calorie information publicly available on or after March 1, 2007, must post such information on its menus and menu boards. The New York State Restaurant Association ("NYSRA") brought suit in federal district court for the Southern District of New York challenging the regulation on preemption and First Amendment grounds. The district court held that Health Code

§ 81.50 as adopted was preempted by 21 U.S.C § 343-1(a)(5) because, to the extent it applied only to restaurants that had voluntarily provided calorie information, it regulated nutrient content claims and was therefore preempted by § 343-1(a)(5). *New York State Restaurant Ass'n v. New York City Board of Health*, 509 F. Supp. 2d 351, 361-63 (S.D.N.Y. 2007) (*NYSRA I*).

Although it found § 81.50 preempted because of the specific way this provision had been written, the district court affirmed the authority of local governments to mandate that restaurants disclose nutritional information: "By making its requirements contingent on a *voluntary* claim, Regulation 81.50 directly implicates § 343(r) and its corresponding preemption provision[, § 343-1(a)(5)]. New York City, although free to enact mandatory disclosure requirements of the nature sanctioned by § 343(q) (and proposed or enacted in other jurisdictions), has adopted a regulatory approach that puts it in the heartland of § 343(r) and has subjected its regulation to preemption under § 343-1(a)(5)." 509 F. Supp. 2d at 363 (emphasis in original; footnote omitted).

E. New York City's Modified Calorie Disclosure Regulation and This Action

The City modified the regulation in accordance with the district court's opinion and did not thereafter pursue an appeal of the judgment in *NYSRA I*. Thus, the current version of Regulation 81.50 requires chain restaurants with 15 or more establishments nationally that sell standardized meals to post calorie content information in their menus and on their menu boards:

> All menu boards and menus in any covered food service establishment shall bear the total number of calories derived from any source for each menu item they list. Such information shall be listed clearly and conspicuously, adjacent or in close proximity such as to be clearly associated with the menu item . . . .

Reg. 81.50(c).

NYSRA again filed an action to declare the new Regulation 81.50 preempted by federal law and/or unconstitutional, and to enjoin its enforcement. *New York State Restaurant Ass'n v. New York City Board of Health*, No. 08 Civ. 1000 (RJH), 2008 WL 1752455, at *1 (S.D.N.Y. April 16, 2008) (*NYSRA II*). The district court concluded that the new Regulation 81.50 is not preempted by the NLEA because that statute explicitly leaves to state and local governments the power to impose mandatory nutrition labeling by restaurants. *Id.* at *4-*5. Section 343-1(a)(4), the court noted, preempts any state "requirement for nutrition labeling of food that is not identical to the requirement of [§ 343(q)], except a requirement for nutrition labeling of food which is exempt [from § 343(q)]." Since food served in restaurants is explicitly exempt from § 343(q), the district court determined that "state authority to impose mandatory nutrition labeling on restaurants is necessarily preserved." 2008 WL 1752455, at *4 (citing 136 Cong. Rec. S16607 (Oct. 24, 1990) (Sen. Metzenbaum) ("Because food sold in restaurants is exempt from the nutrition labeling requirements of [§ 343(q)],

the bill does not preempt any State nutrition labeling requirements for restaurants.")).

The district court rejected the argument that mandatory state disclosures are nevertheless preempted by 21 U.S.C. § 343-1(a)(5). As explained above, this section preempts states from regulating nutrient content claims made by a food purveyor, which claims are subject to FDA regulation under § 343(r). *See supra* at 6. The court determined that because the calorie disclosure was mandated by Regulation 81.50, it was not "a claim" made in the label or labeling of food that "expressly or by implication characterizes the level of any nutrient." 2008 WL 1752455, at *4. According to the district court, the term "claim" "carries the connotation of an assertion by a speaker that is voluntary in nature." *Id.* Therefore, the court determined that the mandated disclosure necessarily fell outside the scope of subsection (r), and that states retain the power to require restaurants to disclose nutrition information to consumers. *See id.* A contrary reading of the statute, the court held, "would also create a regulatory vacuum in which neither federal nor state authorities have the power to require restaurants to disclose nutrition information to consumers." A far more persuasive reading, the court found, was that "Congress chose not to exercise this power and explicitly left it to the states to do so." *Id.* at *5.

The district court also found that the required disclosure of calorie information is reasonably related to the City's interest in reducing obesity and providing consumers with accurate nutritional information. Therefore, the court held, Regulation 81.50 does not

unduly infringe the First Amendment rights of NYSRA members. *Id.* at *6-*12.

F. Prior Proceedings in This Court

NYSRA appealed to this Court and sought a stay pending appeal. On April 29, 2008, the Court heard oral argument on the stay application, and during the argument directed counsel for NYSRA to request FDA to submit an *amicus* brief within thirty days, *i.e.*, by May 29, 2008. *See* Letter from Kent A. Yalowitz, Counsel for NYSRA, to Gerald F. Masoudi, Chief Counsel, Food and Drug Division, United States Department of Health and Human Services (April 30, 2008), at 1 (copy docketed in this proceeding). Following the argument, the Court denied NYSRA's stay application, but set an expedited briefing schedule.

Summary of Argument

The district court correctly held that Regulation 81.50 is not preempted under the NLEA. *See infra* Point I. However, the district court's reasoning—in essence, that *mandatory* disclosure by restaurants of the nutrient content of the foods they serve *could not* constitute a "claim" under section 343(r) and therefore is not expressly preempted—fails to recognize that some state or local regulations mandating disclosure of information about the nutrient content of restaurant foods would be preempted under the NLEA as a nutrient content claim. The reason Regulation 81.50 is not expressly preempted is that the listing of "total calories" is the type of information that is a component of *nutrition information* regulated under section 343(q) (rather than a nutrient content claim regulated under

section 343(r)), and the NLEA expressly exempts from preemption state or local requirements for restaurants to provide nutrition information of this type in the labeling of their foods. 21 U.S.C. § 343-1(a)(4). *See infra* Points I.A, I.B.

There are, however, circumstances when a locally mandated statement regarding calorie content, or the amount of another nutrient, may fall within the definition of a *nutrient content claim* under section 343(r), and would therefore be expressly preempted notwithstanding its mandatory nature. *See infra* Point I.C. For example, a statement such as "low in fat" would be a nutrient content claim whether the statement was voluntary or mandatory. Indeed, FDA regulations provide that even quantitative statements of nutrient amounts such as "contains 100 calories" may be nutrient content claims. *See* 21 C.F.R. § 101.13(b)(1). However, the NLEA carves out of the scope of nutrient content claims information that is properly included in required nutrition labeling. Because New York City is requiring the number of calories in foods sold at chain restaurants to be disclosed as mandatory nutrition labeling, and because the fact to be disclosed (quantitative calorie content) is properly included in nutrition labeling, the information to be provided under Regulation 81.50 is not a nutrient content claim and there is no express preemption under 21 U.S.C. § 343-1(a)(5). *See infra* Point I.B. The FDA's reasonable interpretation of the statute and regulations that it administers is entitled to deference. *See infra* Point I.D.

The district court also correctly rejected NYSRA's First Amendment challenge to Regulation 81.50. *See infra* Point II. Because the regulation requires disclo-

sure of accurate, purely factual information to consumers in the context of commercial speech, it need only be reasonably related to the governmental interest in protecting consumers. The regulation meets that test. *See id.*

ARGUMENT

POINT I

NEW YORK CITY'S HEALTH CODE REGULATION 81.50 IS NOT EXPRESSLY PREEMPTED BY THE NLEA

A. Subject to Limitations That Are Not Applicable Here, the NLEA Preserves State and Municipal Power to Mandate Labeling of Restaurant Foods

As explained *supra* at 5-6, the NLEA expressly preempts any state, or political subdivision of a state, "requirement for nutrition labeling of food that is not identical to the requirement of [§ 343(q)], except a requirement for nutrition labeling of food which is exempt under [certain provisions of § 343(q)]." 21 U.S.C. § 343-1(a)(4). Because food served in restaurants is explicitly exempt from § 343(q) under a referenced provision, state and local authority to impose mandatory nutrition labeling on restaurants is necessarily preserved. The NLEA, however, does not exempt from preemption *nutrient content claims* made by restaurants. See 21 U.S.C. § 343-1(a)(5). The key question, then, is whether the requirement in Regulation 81.50(c) that certain restaurants list the "total number of calories . . . for each menu item they list, . . . clearly and

conspicuously, adjacent or in close proximity such as to be clearly associated with the menu item" constitutes "*nutrition information*," as to which New York City is exempted from express preemption under the NLEA, or instead a "*nutrient content claim*" that, under section 343-1(a)(5), is not exempted from preemption.

NYSRA argues in its brief that Regulation 81.50 requires nutrient content claims and so is preempted under 21 U.S.C. § 343-1(a)(5); and it argues that the district court's "voluntary/mandatory" distinction is unworkable. *See* NYSRA Br. at 23-35.* Although the district court was incorrect to view the "voluntary/mandatory" dichotomy as dispositive, NYSRA's preemption analysis itself is incorrect because Regulation 81.50 constitutes a requirement for labeling of nutrition information and, accordingly, is not expressly preempted by the NLEA.

B. Criteria for Exemption of Nutrition Information from Express Preemption Under the NLEA

A statement is nutrition information exempt from the NLEA's preemption provisions if two criteria are met. First, the statement must be "of the type required by [§ 343(q)] that appears as part of the nutrition information required or permitted by . . . paragraph

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* NYSRA argues in its brief that "[b]ecause the [New York City Health] Board elected not to appeal *NYSRA I*, it is bound by the holding in that case that a quantitative statement about the amount of calories is a 'claim.'" NYSRA Br. at 24. FDA expresses no view on that contention.

[(q)]." 21 U.S.C. § 343(r)(1). Second, a state or local regulatory authority must require the statement to be disclosed with regard to restaurant food as part of nutrition labeling (and the information must be disclosed pursuant to that authority). *Id.* §§ 343-1(a)(4) (excepting from express preemption of specified state and local labeling requirements any "requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 343(q)(5)(A)"), 343(q)(5)(A)(i) (exempting from NLEA's labeling requirements food "which is served in restaurants . . . for immediate human consumption"); *see also id.* § 343(r)(1) (a statement that is part of nutrition information of the type required or permitted by § 343(q) to be in food labeling "is not a claim"); 21 C.F.R. § 101.13(c) ("[i]nformation that is required or permitted . . . to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim . . ."). The statement required by Regulation 81.50 satisfies these criteria.

First, section 343(q) explicitly requires as part of the nutrition information required or permitted by that paragraph "the total number of calories . . . in each serving size or other unit of measure of the food." *See* 21 U.S.C. § 343(q)(1)(C); *see also* 21 C.F.R. § 101.9(c)(1) ("The declaration of nutrition information on the label and in labeling of a food shall contain . . . [a] statement of the caloric content per serving."). The quantitative statement of the total number of calories for each menu item prescribed by Regulation 81.50 accordingly satisfies the first prong of the test for exemption from the express preemption provisions of the NLEA.

A statement of the number of calories in a food may in certain circumstances, however, constitute a nutrient content claim. For example, under FDA regulations, the statement "100 calories" on the front of a package next to the product name would be a nutrient content claim, even though the same information as part of nutrition labeling would not be. *See* 21 C.F.R. § 101.13(c) ("Information that is required by or permitted . . . to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim . . . [but] [i]f such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirement of nutrient content claims."). Therefore, it next must be determined whether Regulation 81.50(c) satisfies the second prong of the test for preemption exemption—*i.e.*, whether a state or local regulatory authority is requiring the statement to be disclosed as part of nutrition labeling.

As to the second criterion, Regulation 81.50 was issued by a local regulatory authority and it requires the calorie information to be "listed adjacent or in close proximity such as to be clearly associated with the menu item." Reg. 81.50(c). This placement is consistent with FDA regulations regarding the placement of nutrition labeling information for foods without labels. *See* 21 C.F.R. § 101.45 (nutrition information "should be displayed at the point of purchase by an appropriate means such as by a label affixed to the food or through labeling including shelf labels, signs, posters, brochures, notebooks, or leaflets that are readily available and in close proximity to the foods"); *see also* 21 C.F.R. § 101.10 (Nutrition labeling of restaurant foods) ("Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other

reasonable means."). Thus, both criteria for the nutrition information exemption are satisfied, and there is no express preemption under 21 U.S.C. § 343-1(a)(5).

NYSRA quotes from FDA regulations and a preamble discussion for the proposition that quantitative statements of nutrient content may constitute nutrient content claims. *See* NYSRA Reply Br. at 9-10. FDA agrees with that assertion. However, nothing in any of the authorities cited requires that *any* quantitative statement of nutrient content will *always* be a nutrient content claim, even when part of mandated nutrition labeling. Such an assertion would be contrary to the express language of section 343(r)(1). In addition, NYSRA's objection that its members may be subject to multiple, inconsistent local regulations in the absence of federal preemption, *see* NYSRA Reply Br. at 15-17, simply states a natural consequence of the choice that Congress has made to permit localities to mandate restaurants to disclose nutrition information about the food they serve. The possible difficulties restaurants may have in complying with multiple localities' requirements, however, is not a permissible basis for this Court to reject that legislative determination.

Moreover, the conclusion that a statement is nutrition information exempt from preemption is not altered by the fact that, whereas the relevant statutory provision refers to disclosures that "appear[] as part of the nutrition information," 21 U.S.C. § 343(r)(1), the corresponding regulation refers to statements that "appear[] as part of the nutrition label." 21 C.F.R.

§ 101.13(c).* Much restaurant food does not have a "label" that is "written, printed, or graphic matter upon the immediate container of any article," 21 U.S.C. § 321(k), so that, as NYSRA observes, the regulation's use of the term "label," if construed narrowly, could be read to eliminate most restaurant food from the statutory carve-out of certain "nutrition information" from the scope of nutrient content claims.

Such a narrow reading, however, would be contrary both to the broader statutory and regulatory scheme, and to FDA policy. Indeed, the FDA regulations themselves elsewhere make clear that nutrition information for non-packaged foods, when required, is to appear in other forms of labeling (*e.g.*, a tag attached to the product, or a sign or booklet at point of purchase) in the absence of a label. *See* 21 C.F.R. §§ 101.9(a), 101.10, 101.45. Moreover, as noted above, the corresponding provision in the NLEA uses the unambiguously broad term "nutrition information." *See* 21 U.S.C. § 343(r)(1) ("appears as part of the nutrition information"). Because mandatory nutrition information on restaurant food is excluded from federal regulation under the NLEA, *see* 21 U.S.C. § 343(q)(5)(A)(i), reading the regulation as NYSRA proposes would exclude most restaurant food from state and local regulation of labeling requirements, and therefore from the reach of *all* governmental authority to require nutrition labeling, other than under the procedures by which states

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* Both the statute and the regulation provide that the statements they describe are not "claims," which, as discussed *supra* at 5-6, are subject to exclusive federal regulation.

and their political subdivisions may petition for an exemption from federal preemption. *See* 21 U.S.C. § 343-1(b).

This reading, however, is contrary to the plain text of the statute and its broader purpose, and is not compelled by the regulation's text. There is no indication that the FDA intended or sought to use regulations to narrow the scope of the statute's preservation of local control over restaurant labeling; the preambles to the proposed and final rules that included this regulation contain no discussion of this issue, which strongly suggests a lack of any intent by FDA to so narrow the statutory definition of nutrition information, and thereby to essentially negate the exemption from the preemption provision of 21 U.S.C. § 343-1(a)(4). *See* 56 Fed. Reg. 60421, 60424 (Nov. 27, 1991) (proposed rule); *see also* 58 Fed. Reg. 2302 (Jan. 6, 1993) (final rule). Thus, section 101.13(c) should be read in tandem with the statute and consistent with the overall regulatory scheme to mean that a quantitative statement of the amount of a nutrient in a food is not a nutrient content claim when it is part of nutrition labeling consisting of the types of statements required or permitted under 21 U.S.C. § 343(q), and when it appears, for packaged foods, in the nutrition information section of the food label or, for non-packaged foods that bear no label, as part of the nutrition information for the food in a place appropriate for such information at the point of purchase. In other words, FDA interprets the term "nutrition label" as used in section 101.13(c) to include, in the context of restaurant food, nutrition information whose disclosure is required by a state or local regulatory body, whether it is placed somewhere that meets the narrow definition of 'label' advanced by NYSRA, or

whether it instead is placed, as here, in appropriate labeling. For restaurants, a menu or menu board is an entirely permissible means of such disclosure.

C. Whether a Statement is Mandatory or Voluntary Is Relevant But Not Dispositive

The district court's mandatory/voluntary dichotomy is relevant to the second prong of the analysis (whether a state or local regulatory authority requires the statement to be disclosed as part of nutrition labeling) but is not the sole criterion for distinguishing nutrition information (which cities and states are not expressly preempted from mandating be disclosed) from nutrient claims under section 343(r) (which are expressly preempted from local regulation). For example, if a state were to require qualitative statements regarding nutrient levels (*e.g.*, to describe certain foods as "low fat"), those statements would be nutrient content claims because they expressly "characterize the level of any nutrient," 21 U.S.C. § 343(r)(1), 21 C.F.R. § 101.13(b), and they are not "of the type required by [§ 343(q)]," to be in nutrition labeling, 21 U.S.C. § 343(r)(1), despite being mandated by the state.

Further, both the NLEA and FDA regulations indicate that placement of the statement in the place designated for nutrition information is part of the criteria for distinguishing nutrition information from nutrient content claims. Thus, § 343(r) provides: "A statement of the type required by paragraph (q) *that appears as part of the nutrition information* required or permitted by such paragraph is not a claim which is subject to this paragraph . . . ." 21 U.S.C. § 343(r)(1) (emphasis added); *see also* 21 U.S.C. § 343(q)(1)(A) (providing that the Secretary may by regulation

establish requirements for presentation of nutrition information). Similarly, FDA regulations provide that "information that is required by or permitted . . . to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim . . . [but] [i]f such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirement of nutrient content claims." 21 C.F.R. § 101.13(c); *see also* 58 Fed. Reg 2302, 2303 (Jan. 6, 1993) (noting that "identical information" could be nutrition information or a nutrient content claim depending on its placement on the label) (citing 136 Cong. Rec. H5841 (July 30, 1990) (statement of Rep. Waxman)).*

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* Although neither the parties nor the district court have addressed the issue, certain local regulations mandating restaurant disclosures or statements could be impliedly preempted under the FDCA even though not expressly preempted by the NLEA. *See supra* at 6-7; *see also Sprietsma v. Mercury Marine, a Div. of Brunswick Corp.*, 537 U.S. 51, 65 (2002) (inclusion of express preemption provision does not bar ordinary working of "conflict" or "implied" preemption principles). The NLEA provides that it should not be construed to preempt state laws, other than by virtue of the NLEA's express preemption provisions. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353, 2364. The NLEA further provides, however, that the statute does not affect express or implied preemption under other provisions of the FDCA that were not amended by the NLEA. *Id.* § 6(c)(3). Thus, any state or local food labeling regulation, even if expressly exempted from

D. FDA's Views Are Entitled to Deference

As the foregoing discussion makes clear, determining whether New York's Regulation 81.50 is expressly preempted under the NLEA requires consideration of a complex federal statutory and regulatory scheme whose interpretation and application are vested in the FDA. To the extent the Court finds more than one interpretation permissible under the NLEA's and federal regulations' plain meaning, the FDA's views are entitled to deference under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Under *Chevron*, if the statute is silent or ambiguous on the matter at issue, the courts will uphold the agency's interpretation if it is "based on a permissible construction of the statute." 467 U.S. at 843; *see also Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 739 (1996) ("It is our practice to defer to the reasonable judgments of agencies with regard to the meaning of ambiguous terms in statutes that they are charged with administering."). Courts give weight to the agency's interpretation of a statute it administers because of the "presumption that Congress, when it left ambiguity in a statute meant for implementation by an agency, understood that the ambiguity would be resolved, first and foremost, by the agency, and desired the agency (rather than the courts) to possess whatever degree of discre-

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preemption pursuant to the NLEA, that renders food labeling false or misleading, for example, would be impliedly preempted under the FDCA, 21 U.S.C. § 343(a).

tion the ambiguity allows." *Smiley*, 517 U.S. at 740-41. Courts similarly accord deference to an agency's interpretation of its regulations. *Auer v. Robbins*, 519 U.S. 452, 461-62 (1997); *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512-13 (1994).

As Regulation 81.50 has just taken effect, FDA necessarily has not had prior occasion to assess whether the regulation is consistent with, or preempted by, the NLEA and related FDA regulations. Rather, the FDA's views on these questions are set forth herein in response to the Court's request of April 29, 2008. The recency of the FDA's views on the precise question presented should have no effect on the deference due here, because there "is simply no reason to suspect that the interpretation does not reflect the agency's fair and considered judgment on the matter in question." *Auer*, 519 U.S. at 462 (affording deference to agency interpretation first expressed in *amicus* brief in case before court). Accordingly, *Auer* dictates affording *Chevron* deference to the FDA's views here.

Even if the Court concludes that *Chevron* is not applicable, it should at a minimum defer to the agency's interpretation under the standards set forth in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). *See Schneider v. Feinberg*, 345 F.3d 135, 143 (2d Cir. 2003) ("Interpretive guidelines that lack the force of law but nevertheless 'bring the benefit of [an agency's] specialized experience to bear' on the meaning of a statute, are still entitled to 'some deference.' "). In *Skidmore*, the Supreme Court recognized that agency interpretations "constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance." 323 U.S. at 140. The Supreme Court there-

fore held that such agency interpretations are given "considerable and in some cases decisive weight," depending upon the "thoroughness evident in [the agency's] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade." *Id.*

POINT II

REGULATION 81.50 DOES NOT VIOLATE THE FIRST AMENDMENT

The district court was correct to hold that Regulation 81.50 does not violate the First Amendment rights of NYSRA or its members. *See* 2008 WL 1752455, at *6-*12. As the district court held, *id.* at *6, Regulation 81.50 implicates commercial speech, and regulations affecting commercial speech are subject to less stringent constitutional requirements than those that affect other forms of speech. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 562-63 (1980); *National Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 113 (2d Cir. 2001), *cert. denied*, 536 U.S. 905 (2002). Furthermore, within the class of regulations affecting commercial speech, there are "material differences between [purely factual and uncontroversial] disclosure requirements and outright prohibitions on speech." *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 650 (1985). Regulations that compel "purely factual and uncontroversial" commercial speech are subject to more lenient review than regulations that restrict accurate commercial speech, and will be sustained if they are "reasonably related to the State's interest" in protecting consumers. *Id.* at 651. As this Court has held, "[c]ommercial disclosure requirements

are treated differently from restrictions on commercial speech because mandated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interests . . . ." *Sorrell*, 272 F.3d at 113-14.

Regulation 81.50 compels only disclosure of "purely factual and uncontroversial" commercial information—the calorie content of restaurant menu items. The regulation also addresses a state policy interest in attacking obesity among its citizens by making accurate calorie information available to consumers. Because there is a "rational connection" between the disclosure requirement and the City's purpose in imposing it, *see Sorrell*, 272 F.3d at 115, Regulation 81.50 passes constitutional muster.* *Cf. Zauderer*, 471 U.S. at 651 n.14 (rejecting the contention that the Court should subject disclosure requirements to a strict "least restrictive means" analysis under which they must be struck down if there are other means by which the State's purposes may be served, and distinguishing *Central Hudson*, 477 U.S. at 565).

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* This Court's decision in *Sorrell* is on all fours with the instant dispute, and thus controls the outcome here, notwithstanding NYSRA's argument that a different result is compelled by *United States v. United Foods, Inc.*, 533 U.S. 405 (2001), and *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996). *See* NYSRA Reply Br. at 24-27. *International Dairy* preceded *Sorrell* so by definition does not disturb it, and NYSRA has not identified any aspect of *United Foods* that undermines this Court's holding in *Sorrell*.

CONCLUSION

Because Regulation 81.50(c) is not expressly preempted under the NLEA and is consistent with the First Amendment, the Court should affirm the district court's judgment.

Dated: New York, New York
May 29, 2008

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(C) of the Federal Rules of Appellate Procedure, the undersigned counsel hereby certifies that this brief complies with the type-volume limitation of Rule 32(a)(7)(B). As measured by the word processing system used to prepare this brief, there are 6185 words in this brief.

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ADDENDUM

21 U.S.C. § 343. Misbranded food

A food shall be deemed to be misbranded—

* * *

(q) Nutrition information

(1) Except as provided in subparagraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides—

(A)(i) the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or

(ii) if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food,

(B) the number of servings or other units of measure per container,

(C) the total number of calories—

(i) derived from any source, and

(ii) derived from the total fat,

in each serving size or other unit of measure of the food,

(D) the amount of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars,

dietary fiber, and total protein contained in each serving size or other unit of measure,

(E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under this chapter before October 1, 1990, if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices.

* * *

(5)(A) Subparagraphs (1), (2), (3), and (4) shall not apply to food—

(i) which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments,

* * *

(r) Nutrition levels and health-related claims

(1) Except as provided in clauses (A) through (C) of subparagraph (5), if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication—

(A) characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food unless the claim is made in accordance with subparagraph (2), or

(B) characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food

to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or (5)(D).

A statement of the type required by paragraph (q) of this section that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph and a claim subject to clause (A) is not subject to clause (B).

* * *

(5)(B) Subclauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do not apply to food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments.

21 U.S.C. § 343-1. National uniform nutrition labeling

(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

* * *

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 343(q)(5)(A) of this title, or

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title, made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

21 C.F.R. § 101.9. Nutrition labeling of food

(a) Nutrition information relating to food shall be provided for all products intended for human consumption and offered for sale unless an exemption is provided for the product in paragraph (j) of this section.

* * *

(2) When food is not in package form, the required nutrition labeling information shall be displayed clearly at the point of purchase (e.g., on a counter card, sign, tag affixed to the product, or some other appropriate device). Alternatively, the required information may be placed in a booklet, looseleaf binder, or other appropriate format that is available at the point of purchase.

* * *

(c) The declaration of nutrition information on the label and in labeling of a food shall contain . . .

(1) "Calories, total," "Total Calories," or "Calories": A statement of the caloric content per serving. . . .

21 C.F.R. § 101.10. Nutrition labeling of restaurant foods

Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in § 101.13 or in subpart D of this part) or a health claim (as defined in § 101.14 and permitted by a regulation in subpart E of this part) is made, except that information on the nutrient amounts that are the basis for the claim (e.g., "low fat, this meal provides less than 10 grams of fat") may serve as the functional equivalent of complete nutrition information as described in § 101.9. Nutrient levels may be determined by nutrient data bases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means

21 C.F.R. § 101.13. Nutrient content claims—general principles

(a) This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale, including conventional foods and dietary supplements.

(b) A claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36 (that is, a nutrient content claim) may not be made on the label or in labeling of foods unless the claim is

made in accordance with this regulation and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium" or "contains 100 calories."

(2) An implied nutrient content claim is any claim that:

(i) Describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"); or

(ii) Suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams (g) of fat").

* * *

(c) Information that is required or permitted by § 101.9 or § 101.36, as applicable, to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

* * *

21 C.F.R. § 101.45. Guidelines for the voluntary nutrition labeling of raw fruits, vegetables, and fish

(a) Nutrition labeling for raw fruits, vegetables, and fish listed in § 101.44 should be presented to the public in the following manner:

(1) Nutrition labeling information should be displayed at the point of purchase by an appropriate means such as by a label affixed to the food or through labeling including shelf labels, signs, posters, brochures, notebooks, or leaflets that are readily available and in close proximity to the foods. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media.

* * *

ANTI-VIRUS CERTIFICATION

Case Name: NYS Rest. Assoc. v. NYC Bd. of Health

Docket Number: 08-1892-cv

I, Louis Bracco, hereby certify that the Amicus Brief submitted in PDF form as an e-mail attachment to **civilcases@ca2.uscourts.gov** in the above referenced case, was scanned using CA Software Anti-Virus Release 8.3.02 (with updated virus definition file as of 5/29/2008) and found to be VIRUS FREE.

Louis Bracco
Record Press, Inc.

Dated: May 29, 2008

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
August, 1995; Revised February, 1996

This document has been superceded by Guidance for Industry: A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods, issued April 2008.

Questions and Answers VOLUME II

A Guide for Restaurants and Other Retail Establishments U.S. Department of Health and Human Services Public Health Service Food and Drug Administration August, 1995

PREFACE

The Nutrition Labeling and Education Act of 1990 (the NLEA) and the final regulations to implement the NLEA (January 6, 1993), provide for a number of fundamental changes in how food is labeled, including requiring that nutrition labeling be placed on most foods, requiring that terms that characterize the level of nutrients in a food be used in accordance with definitions established by FDA, and providing for the use of claims about the relationship between nutrients and diseases or health-related conditions. These changes apply to virtually all foods in the food supply, including, in large measure, to foods sold in restaurants. Following publication of the January 6, 1993, final rules, FDA issued technical amendments that correct unintended technical effects contained in several of the various rules in the **Federal Register** of August 18, 1993 (58 FR 44020). Nonetheless, a large number of questions have been raised by industry, consumers, and others concerning the interpretation of these various final rules. Consequently, the Office of Food Labeling (OFL)/Center for Food Safety and Applied Nutrition (CFSAN)/FDA developed the "Food Labeling, Questions and Answers" (August 1993) as an efficient way to provide answers to some of the more common questions that had been raised concerning the food labeling regulations. The agency is now issuing "Food Labeling: Questions and Answers, Volume II; A Guide for Restaurants and Other Retail Establishments" as part of a continuing effort to respond to concerns. In this Guide, FDA responds to questions raised since publication of the first guide, including questions related to the labeling of foods sold in restaurants. "Food Labeling: Questions and Answers, Volume II; A Guide for Restaurants and Other Retail Establishments" is intended only to be guidance to facilitate compliance with the new regulations. It does not bind the agency, nor does it create or confer any rights, privileges, or benefits for or on any person. While "Food Labeling: Questions and Answers, Volume II; A Guide for Restaurants and Other Retail Establishments" represents the best advice of OFL, it does not have the force and effect of law. The interpretations presented herein are obviously subject to

the requirements of law both in the statute and in the regulations. The OFL plans to issue additional editions of "Food Labeling, Questions and Answers" as resources permit. Questions will be collected by OFL from correspondence and other inquiries that it receives. OFL will also consider specific submissions of questions for inclusion in future editions of "Food Labeling, Questions and Answers". Questions concerning the interpretation of the requirements of the food labeling regulations should be submitted to the Office of Food Labeling (HFS-150), Food and Drug Administration, 200 C St. S.W., Washington, DC 20204.

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QUESTIONS AND ANSWERS

VOLUME II

FOOD LABELING

(for restaurants and other retail establishments)

EXEMPTIONS AND SPECIAL LABELING PROVISIONS (21 CFR 101.9(j))

R1.

Question: Do all foods need to bear nutrition labeling?
Answer: No. Exemptions (or special labeling requirements) are provided for:

1. Small businesses based on gross sales (after May 8, 1995, this exemption will apply only to retailers) (# 101.9(j)(1)).
2. Low volume food products (based on the average number of full time equivalent employees (FTE's) and the approximate units of food products sold in the United States) (# 101.9(j)(18)).
3. Foods served or sold in establishments that serve food for immediate consumption (e.g., restaurants, schools, cafeterias, trains, airplanes, and retail stores such as bakeries and deli's that have facilities for immediate consumption) or that are sold for use only in such establishments (# 101.9(j)(2)).
4. Ready-to-eat foods not for immediate consumption (e.g., restaurant-type foods sold by deli's and bakeries that do not have facilities for immediate consumption) that are primarily processed at the retail location or that are portioned and packaged to the consumer's specifications (# 101.9(j)(3)).
5. Foods of no nutritional significance (e.g., plain coffee or tea) (# 101.9(j)(4))
6. Bulk foods for further manufacturing (# 101.9(j)(9))
7. Raw fruits, vegetables, and seafood (covered by voluntary program for display at retail) (# 101.9(j)(10)).
8. Custom processed fish and game meat (# 101.9(j)(11)).
9. Small packages with less than 12 square inches of available label space, (e.g., a pack of gum (# 101.9(j)(13)), provided the label provides consumers with a way to obtain nutrition information for the food, (e.g., address, phone number). If a claim is made, nutrition labeling must be provided according to # 101.9(j)(13).
10. Food sold from bulk containers, provided that nutrition information is provided at point of sale (# 101.9(j)(16)).

Most of these exemptions are contingent on the food not bearing a nutrient content claim, health claim, or other nutrition-related information on its label or labeling. This set of Questions and Answers will focus primarily on the requirements for foods served or sold in establishments with facilities for immediate consumption (# 101.9(j)(2)) and for ready-to-eat foods sold by retail establishments that do not have facilities for immediate consumption (# 101.9(j)(3)). The other exemptions in # 101.9(j) will be discussed only as they apply to foods sold in these types of establishments. Additional information about the exemptions may be found in: Title 21 of the Code of Federal Regulations; Food Labeling, Questions and Answers (Volume I, August 1993); and in the Federal Register documents cited in the preface of this document.

R2.

Question: Would foods that are exempt from nutrition labeling under # 101.9(j) also be exempt from other labeling requirements?
Answer: The exemptions in # 101.9(j) apply only to nutrition labeling requirements when the food bears no claim or other nutrition information.

R3.

Question: Would food served or sold in carry-out boxes, doggie bags, or sanitary wrappers be considered "packaged food?"
Answer: Food sold in a restaurant or other retail establishment (e.g., a bakery or delicatessen) that is sold from behind a counter and placed in a wrapper, carry-out box, or other non-durable container whose sole purpose is to facilitate handling would not be considered "packaged food" and would not need to bear a net weight statement, ingredient declaration, or the other labeling required of packaged foods. However, if consumers make their selections based on the food in its packaged form, e.g., the food is wrapped or boxed by the retailer and sold from a self-service case in a corner of a restaurant, or across the aisle from an in-store deli, the food must bear all required information.

Exemptions

Small Business Exemption (## 101.9(j)(1) and 101.9(j)(18)).

R4.

Question: Does the small business exemption apply to retailers?
Answer: Yes. The small business exemptions based on dollar sales (# 101.9(j)(1)) and on low volume sales/number of employees (proposed # 101.9(j)(18)) both apply to retailers. When a retailer meets the criteria for a small business exemption under # 101.9(j)(1), all foods packaged by the small retailer would be exempt from nutrition labeling. A low volume food product sold by a retailer would be exempt under proposed # 101.9(j)(18) if the retailer meets the criteria for a small business (e.g., less than 100 full-time equivalent employees) and the food packaged by the retailer is a low volume food (e.g., annual sales of less than 100,000 consumer units). However, if the food product bears nutritional claims or other nutrition-related information on its label or labeling, it is not eligible for either exemption.

R5.

Question: A manufacturer who qualifies for a small business exemption sells his product to a large retailer who then repacks it in the deli and places it on self-service shelves. Is the product exempt from nutrition labeling if the retailer puts the small manufacturer's name on the product?
Answer: Yes. As long as the retailer is simply repacking the food into smaller containers and placing the small business's name and address on the packaged food (i.e., the package label bears no name or logo that would tie the product to the larger retailer), the food would retain any exemption it was eligible for under ## 101.9(j)(1) or (18).

R6.

Question: In May of 1994, a small manufacturer was eligible for a small business exemption based on the gross sales criterion in # 101.9(j)(1). Can the manufacturer use the same criterion in determining whether product is exempt from nutrition labeling in May of 1995?
Answer: No. Since May 8, 1995, the exemption based on gross sales (# 101.9(j)(1)) applies only to retailers (i.e., persons who sell product directly to consumers), and the manufacturer's product would need to comply with the requirements for a low-volume product (# 101.9(j)(18)) for it to continue to be eligible for the exemption.

R7.

Question: A small retailer purchases bulk product from a large manufacturer and repacks the product for retail sale using the retailer's name and logo. Is the product exempt from nutrition labeling?

Answer: If the retailer is eligible for the exemption in # 101.9(j)(1) (based on gross sales), product purchased from a large manufacturer but repacked by the retailer would be exempt from nutrition labeling, as long as the package label bears no name or logo that would tie the product to the manufacturer. However, to be eligible for the exemption in # 101.9(j)(18), the product must also meet the definition of low volume products (based on the total number of units of the product sold by the large manufacturer in the United States).

R8.

Question: What are the requirements for the exemption from nutrition labeling for a low volume food product?
Answer: The exemption for low volume food products is based on the average number of full time equivalent employees (FTE's) and the number of units of product sold in the United States. Only those products listed with the Office of Food Labeling are eligible for the exemption. For products marketed prior to May 8, 1994, limits on FTE's and unit sales will be phased-in according to the following provisions:

Compliance Period	FTE's	Units Sold
1995	< 300	< 400,000
1996	< 200	< 200,000
1997	< 100	< 100,000

Products initially introduced after May 8, 1994, must meet the 1997 levels, i.e., < 100 FTE's and < 100,000 units sold.

R9.

Question: Do all firms need to file with FDA for the small business exemption?
Answer: No. Firms eligible for the exemption based on gross sales and firms with less than 10 FTE's and less than 10,000 units do not have to file with the FDA. However, such firms can choose to do so voluntarily in order to establish a record that they are claiming an exemption (attachment E). Also, all importers must file.

R10.

Question: Does the small business exemption apply to restaurants?
Answer: There is a separate exemption from nutrition labeling for foods sold in restaurants of any size, provided the food does not bear a claim (#101.9(j)(2)). These foods do not need the small business exemption. However, to the extent that a restaurant distributes food products for sale outside the restaurant (e.g., through grocery stores), such products may be eligible for an exemption from nutrition labeling under the small business exemption.

Foods Which are Served or Sold in Establishments in Which Foods are Served for Immediate Consumption (# 101.9(j)(2)):

R11.

Question: If a restaurant makes a claim for one item, does it need to provide nutrition information for all the foods it serves?
Answer: No. The exemptions in ## 101.9(j)(2)(I) through (iii) apply to individual food items that are served or sold in a restaurant or similar establishment, not to the establishment. A restaurant need only provide nutrition information for those items that bear a claim. The restaurant may voluntarily provide nutrition information for restaurant foods that do not bear a claim. It should be

noted that the January 6, 1993 final regulations implementing the NLEA currently apply to all forms of restaurant labeling except for menus. Thus, a claim on a menu does not trigger FDA's nutrition labeling or claims requirements. However, States are not prohibited from enforcing these requirements with respect to menus (see Q **R31**). Furthermore, in the FEDERAL REGISTER of June 15, 1993 (58 FR 33055), FDA published a proposal to remove the exemption for claims on menus. Should the agency publish a final regulation deleting the menu exemption, the requirements discussed herein for non-menu labeling (e.g., signs, posters, placards, brochures, banners, etc.) will apply to all forms of labeling, including menus.

R12.

Question: Are foods sold to and used by restaurants in food preparation, but not served to consumers in the package in which they are received, exempt from nutrition labeling, even if claims are made?
Answer: Yes. The exemptions in # 101.9(j)(2)(iv) for foods sold for use only in restaurants but not served directly to consumers in the package received (e.g., large quantity containers) and in # 101.9(j)(2)(v) for foods sold by a distributor who principally sells food to such facilities are not conditional on the absence of claims as are the other exemptions under # 101.9(j)(2) because the consumer will not see these package labels. However, manufacturers, packers, or distributors may wish to place nutrition information on the label of the package or case, or in a flyer in each case of product, for the benefit of the food service operator who may need such information to support any claims made to consumers in the restaurant. Likewise, the restaurateur may require nutrient content information as a condition of purchase.

R13.

Question: How does FDA define "restaurants?"
Answer: "Restaurants" include conventional full service restaurants and other establishments that offer restaurant-type services. The term "restaurant" applies broadly to establishments where food is served or sold for immediate, on-site consumption (e.g., institutional food service establishments, such as schools, hospitals, and cafeterias; transportation carriers, such as trains and airplanes; delicatessens, and catering where there are facilities for immediate consumption on the premises). The definition of "restaurant" extends to establishments where foods are generally consumed immediately where purchased or while walking away (e.g., lunch wagons, cookie counters in a mall, and vending machines, including similar foods sold from convenience stores); and food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices for immediate consumption.

R14.

Question: Are all foods that are sold in restaurants or from other facilities such as vending machines and that do not bear a claim exempt from nutrition labeling?
Answer: No. The exemptions in ## 101.9(j)(2)(I) through (iii) are limited to (1) ready-to-eat foods served in restaurants and in other establishments in which food is sold for immediate human consumption and (2) foods sold for sale or use only in such establishments. Commercially packaged foods such as soft drinks in cans, bags of potato chips, and candy bars that may be sold in restaurants and vending machines but that are also sold through other retail outlets(e.g., grocery stores) must bear nutrition labeling, regardless of whether or not they bear a claim (subject, of course, to the low volume product and small business exemptions).

R15.

Question: Are foods that are served aboard airlines required to have nutrition labeling?
Answer: Food served aboard airplanes and other common carriers is exempt from nutrition labeling under # 101.9(j)(2)(ii) provided it does not bear a claim.

R16.

Question: A restaurant serves a salsa that was commercially manufactured under the restaurant's brand name. The restaurant also offers a bottled salsa for sale to patrons for later use. The food does not bear a claim. To be eligible for an exemption under # 101.9(j)(2), does it matter whether the food is served for immediate consumption or whether it is sold in packaged form?
Answer: No. The exemptions in ## 101.9(j)(2)(I) through (iii) cover foods that are served or sold in restaurants and similar establishments, regardless of whether they are sold in packaged form provided their sale is limited to restaurant establishments. However, FDA strongly encourages that products such as the bottled salsa bear nutrition labeling when they are sufficiently standardized to do so.

R17.

Question: A bottled salsa sold in a restaurant is also sold through conventional retail outlets. The food does not bear a claim. Must the food bear nutrition labeling?
Answer: Yes. The exemption in # 101.9(j)(2)(iii) for foods sold in restaurants specifies that the food be sold only in restaurants. Because the sale of the salsa is not limited to restaurants, both products (i.e., restaurant and retail) must bear nutrition labeling under # 101.9. The exceptions to this requirement would be (1) foods that are packaged differently for use in restaurants compared to the food sold at other retail locations, e.g., catsup, soy sauce, and other condiments packed in decorative containers for table service, and (2) products covered by the small business or low volume products exemptions.

R18.

Question: Would foods sold in a gift shop attached to a restaurant or food items sold from a counter across the aisle from the cash register in a truck stop be considered "restaurant foods?"
Answer: If the retail area is located in close proximity to the restaurant, e.g., across the aisle from the area where food is served, and if it is not operated independently from the restaurant, it could be considered part of the restaurant establishment and the foods sold therein may qualify for the "restaurant food" exemption. However, any food item whose sale is not limited to restaurants would not be a restaurant food and, therefore, would not be eligible for the exemption in # 101.9 (j)(2)(iii).

R19.

Question: Could you elaborate on the types of foods sold in vending machines that are exempt from nutrition labeling?
Answer: Foods that are prepared or dispensed by a vending machine (e.g., soda, coffee, soup, or popcorn that is dispensed into a cup) would be analogous to foods served in a restaurant and, therefore, would be exempt from nutrition labeling requirements provided the food does not bear a claim (# 101.9(j)(2)(ii)). Vending machine foods sold in packaged form (e.g., a salad or sandwich prepared in a commissary) that are similar to foods sold in restaurants are exempt from nutrition labeling requirements under # 101.9(j)(2)(iii) provided the food does not bear a claim and it is not sold through other retail channels (e.g., grocery stores). The exemption for food sold in restaurants and similar establishments, including vending machines, extends to commercially manufactured foods that have been specially packaged for sale only in such establishments. However, FDA strongly encourages that foods that are sufficiently standardized to bear nutrition labeling (e.g., individual serving size cans of soup) do so.

R20.

Question: Could you elaborate on the types of foods that are sold from convenience stores but that would be exempt from nutrition labeling because they are similar to restaurant foods?
Answer: FDA has stated that the exemption from nutrition labeling for such foods should be

limited in scope and that some enforcement decisions will need to be made on a case-by-case basis. Generally, however, the foods covered by this exemption must be of the type served in restaurants or similar establishments (i.e., ready-to-eat, sold for immediate human consumption). Such foods would be expected to be non-standardized (e.g., prepared in a commissary kitchen similar to a restaurant or cafeteria kitchen where foods are assembled by hand and subject to individual product variations) and to have a short shelf-life. Examples of such foods would include: sandwiches; single-serving packages of salads, pies, and puddings; and soups and beverages dispensed into cups, that are in direct competition with foods served in restaurants and that are generally consistent with the above criteria. In contrast, this exemption would not extend to foods that are not ready-to-eat or are not for immediate consumption. As discussed in response to question **R32**, there is a separate exemption from nutrition labeling for ready-to-eat foods not for immediate consumption (e.g., ready-to-eat foods that are processed or prepared at the location from which they are sold but that are sold for later use (# 101.9(j)(3)). Where the food sold in a convenience store is sufficiently standardized to bear nutrition labeling, it should do so, unless otherwise exempt.

R21.

Question: If an exempt sandwich sold in a vending machine or convenience store includes a single serving unit of a condiment, such as mayonnaise, must nutrition labeling be provided on the mayonnaise packet?
Answer: Foods that are eligible for the exemption from nutrition labeling under # 101.9(j)(2), including sandwiches sold from lunch wagons, vending machines, and convenience stores, are exempt in their entirety. Therefore, a mayonnaise packet packaged with a sandwich is also exempt as long as its label does not bear a claim or other nutrition information.

R22.

Question: Would a single serve package of a condiment be exempt from nutrition labeling if it is served on its own, e.g., placed in a bowl on a table?
Answer: Yes. Food that is served in a restaurant or similar establishment is exempt from nutrition labeling provided that the food does not bear a claim (## 101.9(j)(2)(i) and (ii)). Condiments in single serve packages placed in a bowl on a table in a full service restaurant or in a container on a lunch counter or vending facility for consumers to use at their discretion, would be eligible for these exemptions. Likewise, condiments served in larger, multi-serving containers would also be eligible for the exemption under ## 101.9(j)(2)(i) or (ii) provided the food does not bear a claim.

R23.

Question: A single-serve package of a condiment is served or sold in restaurants. It is commercially manufactured, packaged, and labeled. The package label bears a claim. How should nutrition labeling be accomplished for the food?
Answer: In the August 18, 1993, technical amendments (58 FR 44020), FDA amended # 101.9(j)(13)(i)(B) to permit individual serving-size packages of food for use in restaurants and similar situations to use the minimum type size allowed under # 101.2(c)(5) of one thirty-second inch for nutrition labeling provided that the packages have a total area available to bear labeling of 3 square inches or less. If, despite this provision, a small package still cannot comply with nutrition labeling requirements, the person responsible for labeling is advised to write the Office of Food Labeling, FDA (HFS-150), requesting alternative means of compliance in accordance with 101.9(g)(9). (See Q **R66** and **R67**.)

R24.

Question: A restaurant serves a food that is commercially manufactured, packaged, and labeled. The food is served to consumers in the form it was purchased by the restaurant, e.g., individual

serving size packages of condiments are placed in a bowl for consumer use. Would FDA hold the restaurant that serves the food responsible if the label of the food does not meet FDA's requirements, for example, if a package of salad dressing bears a "lowfat" claim but fails to bear nutrition information?
Answer: FDA requires that the label of a food sold in packaged form identify conspicuously the name and place of business of the manufacturer, packer, or distributor (# 101.5). The firm that is so identified is generally the firm that is responsible for insuring that the food is properly labeled.

R25.

Question: Must a restaurant food be ready-to-eat to be exempt under # 101.9(j)(2)?
Answer: Not necessarily. The exemptions for foods served in restaurants and in similar establishments (## 101.9(j)(2)(i) and (ii)) imply that the food is ready-to-eat and is served for immediate consumption. However, a restaurant may also sell foods for carry-out that are not ready-to-eat, e.g., a pizza that is only half cooked or a pie that is frozen. Further, foods sold for use in restaurants may be used as ingredients in the foods a restaurant prepares but are not, themselves, ready-to-eat. Thus, the exemptions for foods sold for sale or use only in restaurants (## 101.9(j)(2)(iii) and (iv)) and for foods sold by a distributor who principally sells food to such facilities (# 101.9(j)(2)(v)) are not limited to ready-to-eat foods.

R26.

Question: Company X operates a large chain of restaurants with different facilities and services at each establishment based on the size of the establishment. Larger establishments have facilities for consuming food on the premises, sell food for "carry-out," and offer home delivery services. Some of the company's smaller retail establishments have no on-site eating facilities and all food sold is for "carry-out" or home delivery. Are the foods sold from these establishments exempt from nutrition labeling under # 101.9(j)(2)?
Answer: In the above example, all foods served in the larger restaurant establishment would be exempt from nutrition labeling provided the food does not bear a claim. Foods sold for carry-out or home delivery from larger establishments (i.e., establishments with facilities for immediate consumption of the food) would also be exempt provided the food does not bear a claim and sale of the food is limited to restaurant-type establishments. Foods sold by an establishment with no tables and chairs would still be eligible for the exemption provided that the food is ready-to-eat and is generally consumed immediately where purchased or while walking away (e.g., pizza sold from a walk-up counter in a mall). This exemption extends to foods sold by establishments that have facilities for delivering ready-to-eat foods to homes and offices for immediate consumption. Ready-to-eat "carry-out" foods would be similar to home-delivery foods, with the consumer doing the delivering, provided the foods are sold for immediate consumption.

R27.

Question: In the preceding example, most of the smaller establishments owned by Company X (i.e., establishments that offer only carry-out and home delivery service) cook, assemble, and otherwise prepare the food on-site. However, a few of the very small locations sell ready-to-eat food for immediate consumption that is prepared at a central commissary and shipped to the retail location. Are these foods still exempt from nutrition labeling under the restaurant food exemption if they do not bear a claim?
Answer: Yes, provided the foods meet the general criteria for restaurant foods, i.e., they are ready-to-eat and sold for immediate consumption. Although foods served or sold in restaurants are frequently prepared on-site, this is not a requirement for this exemption. (There is a separate exemption in # 101.9(j)(3) for restaurant-type foods that are ready-to-eat, not for immediate consumption, and prepared at the retail location from which they are sold (see Q **R32**)).

R28.

Question: Would a ready-to-eat food that is normally sold for immediate consumption by a small carry-out restaurant lose its exemption from nutrition labeling if consumers occasionally purchase the food for later use? For example, if a consumer purchases an extra pizza at lunch-time and takes it home for dinner that night or the next day.
Answer: If a food is consistent with the general requirements for the exemption for restaurant foods, it would not automatically lose its exemption because of a limited number of sales that are different from normal practice. When determining whether a food qualifies for an exemption from nutrition labeling, and which exemption applies, FDA would consider how the food would most often be reasonably expected to be sold (e.g., for immediate consumption).

R29.

Question: Do restaurant foods that make claims need to comply with the same requirements as foods from other sources?
Answer: Restaurant foods that bear a claim must comply with the same definitions for nutrient content claims or qualify to bear health claims under the same authorizing regulations as foods from other sources. At the same time, FDA is providing a measure of flexibility in how restaurateurs determine the nutrient content of their food (e.g., "reasonable basis" for believing a food meets the definition of a claim), and how they communicate this information to consumers (e.g., in a brochure or notebook) (# 101.10). These provisions are discussed in sections II and III of this document.

R30.

Question: When are the labeling requirements for restaurant foods effective? ***Answer:*** The effective dates vary depending on the type of claim being made, the size of the restaurant, and the type of labeling that bears the claim. "Small restaurants" are defined as "firms with 10 or fewer establishments." Larger restaurants have more than 10 establishments. The effective dates FDA established are:

- **May 8, 1993**, for health claims in non-menu labeling in larger restaurants;
- **May 8, 1994**, for health claims in non-menu labeling in small restaurants;
- **May 8, 1994**, for nutrient content claims in non-menu labeling in larger restaurants;
- **May 8, 1995**, for nutrient content claims in non-menu labeling in small restaurants;

Thus, all of these requirements are in effect.

R31.

Question: Can a State require restaurant foods to bear nutrition labeling even if the food is exempt under Federal requirements?
Answer: Yes. The NLEA provided for Federal preemption of State and local requirements that are not identical to the Federal requirement in a number of key areas of food labeling (section 403A (a) of the act). However, sections 403A(a)(4) and (5) of the act provide that State requirements of the type required by 403(q) (nutrition labeling) and 403(r)(1) (claims) would not be preempted for foods that are exempt from the Federal requirements. Thus, even though claims on menus are not currently subject to NLEA, States would be free to apply nutrition labeling and claims requirements to claims on menus. Furthermore, because the act exempts restaurant foods that do not bear a claim from mandatory nutrition labeling, State requirements for the nutrition labeling of such foods would not be preempted. The act also exempts restaurant foods that bear a claim from certain disclosure and referral statements. Thus, State requirements of this type would not be preempted. (The first volume of Questions and Answers, August 1993, N95, incorrectly stated that a State would need to submit a petition, and receive a favorable response to that petition, in order to enforce State requirements for the nutrition labeling of restaurant foods).

Ready-to-eat Foods Not for Immediate Consumption (# 101.9(j)(3)):

R32.

Question: I own a "gourmet-take-away" store. Many of the items sold in the store are ready-to-eat, similar to foods served in restaurants. However, the foods are not usually purchased for immediate consumption. Must these foods bear nutrition labeling?
Answer: It depends. Section 101.9(j)(3) exempts the types of ready-to-eat foods that would have been exempted by ## 101.9(j)(2)(i) or (ii) (i.e., ready-to-eat foods that are served in restaurants and similar establishments and that do not bear a claim) had it not been for the requirement that the food be sold in an establishment that has facilities for immediate consumption. To be eligible for the exemption in # 101.9(j)(3), restaurant-type foods that are sold by retail establishments that do not have facilities for immediate consumption must be: (1) similar to foods served in restaurants, (2) ready-to-eat, (3) primarily processed or prepared at the retail establishment from which they are sold, and (4) not offered for sale outside such establishment. Accordingly, ready-to-eat food that is prepared on-site, and that is sold only from such retail location, is exempt from nutrition labeling under # 101.9(j)(3) provided that it does not bear a claim, regardless of whether or not there are facilities for on-site consumption. Foods that are prepared elsewhere but are portioned and packaged to consumer specifications at retail would fulfill the prepared on-site criterion.

R33.

Question: To be exempt from nutrition labeling under # 101.9(j)(3), foods must be ready-to-eat. Are cold entrees, such as lasagna or pizza, considered ready-to-eat even though they are generally eaten hot?
Answer: As long as the food is fully cooked, it is considered ready-to-eat. For example, a pizza with a raw crust that requires cooking before consumption would not be "ready-to-eat." However, a pizza that is cooked and then cooled would be. While most customers would be expected to reheat the food before consumption, it would not be necessary that they do so.

R34.

Question: Could you elaborate on which foods sold from delis and bakeries that do not have facilities for immediate consumption of food (including independent deli's and bakeries and the deli or bakery cases of retail stores) are exempt from nutrition labeling under # 101.9(j)(3)?
Answer: Foods sold from behind deli and bakery service cases, where the customer must make a selection and indicate the amount of the item desired, are exempt unless the food bears a claim or other nutrition information. When claims or other nutrition information are given, nutrition labeling needs to be displayed clearly at the point-of-purchase. When the deli or bakery foods that are regulated by FDA are packaged for self-service, they are only exempt from nutrition labeling if the product was primarily processed or prepared on-site, and no claims are made for the product. If the food is primarily processed or prepared on the premises from which it is sold, it is exempt from nutrition labeling, regardless of how it is sold (i.e., from behind the counter or pre-portioned packages from a self-service shelf).

R35.

Question: Would bread baked at the retail location qualify as "primarily processed or prepared on-site," if the bakery is using dough that was pre-formed at a different location? What if the bakery adds icing to a cake that was baked elsewhere?
Answer: To meet the criterion for being "primarily processed or prepared on-site," the food must be augmented on site in a manner that changes the nutritional profile of the food, i.e., filling, icing, enrobing. Foods that are assembled on-site meet this criterion even though some components of the food (e.g., the bread or cheese used in a sandwich) were prepared elsewhere.

Similarly, cakes that are custom decorated at the retail location are exempt, even if the cake was baked elsewhere. Garnishing (e.g., adding sesame seeds to bread dough) would fall under the definition of "primarily processed or prepared on-site" if the added food changes the nutritional profile of the finished product. In contrast, if a food is merely portioned on-site or if pre-formed dough or pre-scaled/-molded dough is simply thawed or merely proofed and baked at the retail location, the product is not "primarily processed or prepared on-site," and nutrition labeling is required.

R36.

Question: Is nutrition labeling required for orange juice that is freshly squeezed in the produce section of the retail store?
Answer: No, this product is produced on the premises from raw oranges available in the retail section of the store. It may be collected in containers brought in by consumers or containers available from the retail store. The product need not have nutrition labeling.

R37.

Question: Must cheeses that are cut into slices or wedges and packaged in retail establishments bear nutrition labeling?
Answer: Cheese is generally not processed or prepared on the premises. Therefore, unless it is sold from behind the deli counter, i.e., portioned to consumer specifications, it would not qualify for an exemption under # 101.9(j)(3). When pre-portioned, wrapped, and put out on a self-service counter, it is a packaged food and must meet all labeling requirements.

R38.

Question: Must slices of cheesecake that are cut and packaged in retail establishments bear nutrition labeling?
Answer: If the cheesecake is primarily processed or prepared on the premises, or if it is sold from behind the deli counter, it is exempt under # 101.9(j)(3). If it does not meet either of these criteria, it must bear full labeling. As with cheese, when pre-portioned, wrapped, and put out on a self-service counter, it is a packaged food and must meet all labeling requirements.

R39.

Question: A deli purchases 6 and 8 lb loaves of bread that it cuts and sells by unsliced, random weight portions. Is nutrition labeling required for the bread, and if so, how can the deli declare "Serving size" and "Servings per container" for the unsliced, random weight portions? ***Answer:*** Nutrition labeling would be required on the cut pieces when they are packaged and put out on a self-service shelf, or if claims are made on the product when sold from behind the counter. When labeling is required, the serving size for the unsliced bread should be based on the reference amount (e.g., "2 oz (56 g/1 inch slice)"), and the "Servings per container" could say "varied," so that the same nutrition label could be used on all random weight portions.

R40.

Question: Is nutrition labeling required for foods sold in a salad or soup bar in a retail store?
Answer: Unpackaged ready-to-eat foods available for self-service from salad and soup bars in a retail store (i.e., a grocery store that does not have facilities for immediate consumption) are generally exempt under # 101.9(j)(3) since the foods are of the type often sold from a service counter or deli case and are portioned to consumer specifications (even though it is the customer, not store personnel, who is portioning the food item). This exemption includes ready-to-eat food, not for immediate consumption, that is primarily processed or prepared at the retail location from which it is sold, regardless of whether it is sold wrapped or self-service. If the food is ready-to-eat and is sold for immediate consumption, it may also qualify for the restaurant food exemption,

even if it is sold from a retail establishment with no facilities for immediate consumption. (See, e.g., foods sold in convenience stores that are in direct competition with restaurant foods (Q **R13**)). The above exemptions are dependent on the food not bearing a claim or other nutrition information. If a claim is made (e.g., "low fat pasta salad"), or when other nutrition information is provided, the above exemptions are lost, and nutrition information must be provided.

R41.

Question: When party platters of vegetables and dip or cheeses are made up in the deli or produce section of a retail store, must the platters bear nutrition labeling? On vegetable platters, does it make a difference if the dip is prepared in the store or is a commercially prepared product?
Answer: Platters prepared or assembled at a retail location and sold from such retail location are exempt under # 101.9(j)(3), regardless of whether the platter includes a commercially processed food component, such as a dip. In contrast, platters that are prepared in a central commissary and shipped to the retail store must bear nutrition labeling (except platters containing only fresh fruits or vegetables that are exempt under the voluntary nutrition labeling program # 101.9(j)(10)).

Foods Sold from Bulk Containers (# 101.9(j)(16)):

R42.

Question: How should nutrition labeling be accomplished for foods sold from bulk containers?
Answer: Section 101.9(j)(16) allows foods sold from bulk containers to display the required nutrition information on the outside of the container or on posters, counter cards, tags, or similar measures. The containers these foods are put into when sold to the consumer do not need to bear nutrition labeling as long as the required nutrition information is displayed at point-of-purchase (i.e., plainly in view by the bulk containers).

R43.

Question: If a bulk food is repacked at the retail level and sold in packaged form instead of from the bulk container, do the individual packages have to carry nutrition labeling?
Answer: Yes. When foods are received by a retail store in bulk form and repacked for sale to consumers as a packaged food, the package must meet all mandatory labeling requirements.

R44.

Question: When placing nutrition labeling on bulk foods, how should the number of servings per bulk container be declared?
Answer: The number of servings in a bulk container will vary according to the fill of the container, and such a number is of little or no usefulness to consumers. Thus, FDA intends to propose in the Federal Register the possible use of the term "varied" or other options for expressing servings per container in this situation. Pending such rulemaking, FDA would be unlikely to object to a statement that the "Servings per container" are "varied" on bulk food containers or on random weight portions of foods repackaged by the retailer.

R45.

Question: Who is responsible for providing nutrition information for bulk foods?
Answer: The retailer is responsible for displaying the nutrition information in the required format on or adjacent to the bulk container. The information may be obtained/provided by either the supplier or retailer. The decision as to who actually develops the information is up to those parties involved.

R46.

Question: If a co-op sells bulk foods directly to consumers or consumer groups, must the bulk container bear nutrition labeling?
Answer: Yes. Subject, of course, to the exemptions for small businesses and low volume products.

Voluntary Nutrition Labeling of Raw Fruits, Vegetables and Fish (# 101.9(j)(10) and # 101.45):

R47.

Question: Will posting of nutrition labeling for all raw fruit, vegetables, and fish be required?
Answer: No. The program is voluntary as long as there is substantial compliance by the retail food industry. FDA is required to survey every two years to see if a substantial proportion of retailers are providing nutrition labeling for the 20 most frequently consumed fresh vegetables, fruits, and raw fish.

R48.

Question: What are the 20 most frequently consumed raw *vegetables, fruits, and fish*? Are they determined on a regional basis?
Answer: The 20 foods for each group are identified in # 101.44. The same list is to be used nationwide. *Vegetables:* Potato, iceberg lettuce, tomato, onion, carrot, celery, sweet corn, broccoli, green cabbage, cucumber, bell pepper, cauliflower, leaf lettuce, sweet potato, mushrooms, green onion, green (snap) beans, radishes, summer squash, and asparagus. *Fruits:* Banana, apple, watermelon, orange, cantaloupe, grapes, grapefruit, strawberries, peach, pear, nectarine, honeydew melon, plums, avocado (California), lemon, pineapple, tangerine, sweet cherries, kiwi fruit, and limes. *Fish:* Shrimp, cod, pollack, catfish, scallops, Atlantic/coho salmon, flounder, sole, oysters, orange roughy, Atlantic/Pacific and jack mackerel, ocean perch, rockfish, whiting, clams, haddock, blue crab, rainbow trout, halibut, and lobster. On July 18, 1994 (59 FR 36379), FDA proposed that the list for the 20 most frequently consumed raw fish be modified to read as follows: Shrimp, cod, pollack, catfish, scallops, salmon (Atlantic/coho, chum/pink, sockeye), flounder/sole, oysters, orange roughy, mackerel (Atlantic/Pacific), ocean perch, rockfish, whiting, clams, haddock, blue fish, rainbow trout, halibut, lobster, and swordfish.

R49.

Question: Can retailers provide nutrition labeling for raw fruit, vegetables, and fish that are not among the top 20 items?
Answer: Yes. The names and descriptions of these foods should clearly identify them as distinct from the foods among the most frequently consumed list for which FDA has provided data (# 101.45(c)(1)). Nutrition labeling values for foods not on FDA's lists are subject to the compliance provisions of # 101.9(g).

R50.

Question: How does FDA define "raw fruit and vegetables" for the voluntary nutrition labeling program? Are fresh herbs and nuts included under the voluntary nutrition labeling program if they are sold in the produce section of retail stores?
Answer (revised 2/96): The NLEA provides for voluntary nutrition labeling of "raw agricultural commodities and raw fish." The act defines "raw agricultural commodities" as any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing. Therefore, fruit and vegetables that receive little or no processing and no heat treatment, regardless of whether the fruit and vegetables are waxed, are subject to the voluntary program. In addition, for ease of administration the agency has chosen to draw a practical line in terms of retail selling practices and program implementation by including raw fruit and vegetables that are sold in the producesection and that are peeled, trimmed, cut and/or

packaged with no added ingredients (e.g., carrot sticks, mixed salad greens) in the voluntary program when no claims are made for the product. When claims are made, nutrition labeling is required on the package unless the the required nutrition information is provided on a poster or other means as specified in # 101.45. Accordingly, fresh herbs and nuts (e.g., walnuts, peanuts) that have no added ingredients, such as salt, and that are sold in the produce section would be exempt from nutrition labeling under the voluntary program. However, when shelled or unshelled nuts or produce are processed in a manner other than mixing with other raw produce items, peeling, trimming , or cutting, (*e.g.*, dried fruit, roasted nuts, frozen melon balls), nutrition labeling is required under # 101.9.

R51.

Question: Is nutrition labeling still voluntary on packages of raw vegetables or fruits when processed foods, such as salad dressings and croutons, are added to the package?
Answer: When processed foods, such as salad dressings or croutons, are added to packages of raw vegetables or fruits, the product is considered to be a multi-ingredient processed packaged food and is no longer part of the voluntary program. Therefore, nutrition labeling is mandatory for the entire contents of the package. (Subject, of course, to the exemption for ready-to-eat food that is primarily processed or prepared at the retail location and the small business exemptions.)

R52.

Question: Would the packaged salad with dressing be considered ready-to-eat if consumers have to open the package of dressing and add it to the salad greens themselves?
Answer: Because restaurant salads may be served with the dressing on the side or the croutons in a side package, packages of salads prepared in the retail establishment would be considered ready-to-eat when the only preparation needed by the consumer is adding the dressing or croutons. In contrast, products that require a significant amount of assembly or preparation (e.g., a pizza kit) would generally not be considered ready-to-eat.

R53.

Question: I understand that adding salad dressing to a package of greens makes the food a multi-ingredient processed food and nutrition labeling is required for the entire contents of the package. Does the requirement change if the packaged salad contains a packet of salad dressing that already bears nutrition labeling?
Answer: No. Nutrition labeling is still required for both the greens and the salad dressing. However, # 101.9(h)(1) allows separately packaged ingredients that are intended to be eaten at the same time to be labeled individually or with a composite value. Therefore, the greens and salad dressing can be labeled individually. If the nutrition label on the packet is visible at the point of purchase, the information on the dressing need not be reprinted on the outer bag.

R54.

Question: Is nutrition labeling required for candied or caramel apples sold in the produce department?
Answer: Yes. These products are multi-ingredient processed food products. Therefore, nutrition labeling is mandatory.

R55.

Question: Is nutrition labeling required for raw, frozen fish that are packed or repacked by the retailer and sold in the frozen food section of the retail store?
Answer: Raw single-ingredient fish that are packaged by the retailer, whether fresh or frozen, fall under the voluntary nutrition labeling program. However, for the retail store to be in compliance with the voluntary program, the nutrition labeling information must be available at point of

purchase (i.e., be displayed in close proximity to the product) of both the fresh and frozen fish. It may be necessary for some retail stores to display signs/brochures with the nutrient data for fish in the frozen food section as well as the fresh fish section of the store. In contrast, raw frozen fish that are packaged by a manufacturer (e.g., packaged in a box with a printed label and brand name) come under the mandatory nutrition labeling program.

R56.

Question: Is nutrition labeling required for crab meat that is canned and pasteurized, but not shelf-stable?
Answer: Pasteurized crab meat that is not shelf-stable and is sold on ice or refrigerated is included under the voluntary nutrition labeling program, whereas canned crab meat that is shelf-stable must bear nutrition labeling.

R57.

Question: Are steamed shrimp exempt from nutrition labeling if they are purchased from a manufacturer and repacked in the retail store for sale from either the fresh fish or deli counters? Would it make a difference if the retailer adds a seasoning mix when steaming the shrimp or if a cocktail sauce is added to the package?
Answer: Plain, thermally processed shelled or unshelled lobster, crab, and shrimp are included in the voluntary nutrition labeling program when sold in either the fresh fish or deli sections of the store. However, consistent with earlier answers for fruit and vegetable products, when a food is composed of more than one ingredient, some of which are not included in the voluntary program (such as a seasoning mix or cocktail sauce), it must bear nutrition labeling. These added ingredients would generally alter the nutrient content of the product so that the nutrient values posted for the voluntary program would no longer accurately represent the finished product. However, if the finished product meets the criteria for a ready-to-eat food, primarily processed and prepared at the location from which it is sold (e.g., steamed, spiced shrimp prepared in-house), it may be exempt from nutrition labeling under # 101.9(j)(3) (see Q **R32**).

Labeling

Nutrition Label Format (# 101.9(d)):

R58.

Question: We package fresh tomatoes and want to put nutrition labeling on the package. Should we follow the guidelines for the voluntary program for raw fruit, vegetables, and fish (# 101.45) or the nutrition labeling format required by # 101.9?
Answer: When providing nutrition information on the package, even when nutrition labeling is otherwise voluntary, the information should be presented in a format that is consistent with the format requirements in # 101.9(d).

R59.

Question: We produce a cookie assortment containing various percentages of 6 different cookies. What nutrition format should be used?
Answer: The manufacturer may choose to use: (1) a separate Nutrition Facts label for each variety of cookie in the package, (2) an aggregate label (i.e., a single Nutrition Facts panel including nutrient content information and % Daily Values in separate columns for each variety), or, (3) if it is likely that one person would eat an assortment of the cookies at the same time, a composite label that provides one set of nutrition information based on a weighted average of all of the cookies in the assortment.

R60.

Question: I use a single box to package a variety of different products (e.g., cherry pie, apple pie, cheese cake, etc.). The box is partially pre-labeled, i.e., it bears nutrition labeling in the aggregate format for all possible products. When product is packaged, I print the identity statement for the food on the principal display panel. Must the Nutrition Facts panel be marked or highlighted at the time of packaging to indicate which product is in the package? ***Answer:*** No, the statement of identity on the principal display panel along with the statement of identity above each column of nutrient values in the aggregate Nutrition Facts panel will provide adequate information for the consumer to determine which nutritional values in the aggregate label apply to the contents of the package.

Gift Packages (# 101.9(h)(3)):

R61.

Question: What is the correct way to label a gift basket that contains a variety of foods, candies, and liquors of various sizes? Does nutrition labeling have to be provided for each individually wrapped product, and are such packages considered multi-packs?
Answer: Nutrition labeling of gift food packages is addressed in # 101.9(h)(3) which:

1. allows nutrition information to be placed on labeling inside the package,
2. provides for standardized serving sizes when there is no reference amount appropriate for the variety of foods in the gift pack,
3. allows number of servings per container to be listed as "varied,"
4. allows nutrition information to be given as a composite for categories of foods in the gift pack that have similar dietary uses and similar nutritional characteristics (e.g., assorted chocolate candies, assorted cheeses), and
5. does not require declaration of nutrients in free promotional items or items used in small quantities to enhance the appearance of the gift package.

The required nutrition information for different foods may be put on a brochure or package insert using the aggregate display illustrated in # 101.9(d)(13)(ii). Listing the servings per container as "varied" allows use of the same nutrition label on packages of varied sizes. If some individually wrapped food items in the gift pack bear nutrition labeling, that information need not be repeated with the nutrition information provided for the unlabeled foods, e.g., on the outside of the gift pack or on a package insert. Further, the labeling of all malt beverages, regardless of alcohol content, and of liquors and wines containing 7 percent or more by volume of alcohol is regulated by the Bureau of Alcohol, Tobacco, and Firearms (BATF). BATF does not require that the products it regulates bear nutrition labeling.

R62.

Question: A retailer assembles gift packages containing a mixture of prepackaged and pre-labeled foods from the following categories: (1) Food items in packages that bear Nutrition Facts in accordance with # 101.9, (2) packages with less than 12 square inches of available label space that contain a phone number where nutrition information may be obtained, (3) packages labeled before May 8, 1994, with the old nutrition label format, and (4) packages labeled before May 8, 1994, that do not bear nutrition labeling. What are the nutrition labeling requirements for gift packages containing these foods when the gift package is assembled after August 8, 1994?
Answer: Gift packages that are assembled after August 8, 1994, are required to bear nutrition labeling in accordance with current labeling regulations. The following rules apply to the above categories:

1. When individual food packages within a gift package bear complete nutrition labeling, the nutrition information need not be repeated on the outer wrapper or in a package insert, even when such means are used to convey nutrition information on other products within the gift

package.

2. Available label space is not an issue for most gift packages since the required information may be placed on the larger outer wrapper or in a package insert. Therefore, when packages with less than 12 square inches of available label space are added to a gift package, the nutrition information should be obtained from the manufacturer and placed on or within the gift package. Free promotional items and items used in small quantities to enhance the appearance of the gift package are excused from this requirement (# 101.9(h)(3)(v)).
3. Because, in part, the old nutrition label does not provide all of the nutrition information now required on nutrition labeling (e.g., percent Daily Value), those labels cannot be used in lieu of the new nutrition labels. However, the agency will not object to the use of packaged foods that bear the old nutrition label in gift packs assembled after August 8, 1994, provided that the gift pack provides nutrition labeling on the outer wrapper or in a package insert that meets the requirements of new # 101.9.
4. Nutrition labeling must be placed on the outer wrapper or on a package insert for all foods in a gift package (except free promotional items and items used in small quantities to enhance the appearance of the gift package) that do not bear the required nutrition information on the package label. This is true for foods packaged before May 8, 1994, or anytime after that date, when they are incorporated in a gift package.

R63.

Question: Is nutrition labeling required for fresh fruit included in a gift package?
Answer: Nutrition labeling is not required when the entire package is made up of fresh fruits (which fall under the voluntary nutrition labeling program) or when the fruit is packed with other processed foods that are intended to be eaten separately. However, if the fruit is included as one part of a kit with more than one ingredient, and some of the other ingredients are not subject to the voluntary labeling exemption, nutrition labeling is required (e.g., apples and caramel sauce).

R64.

Question: I assemble gift packs using prepackaged foods manufactured by other companies. Labeling on my part is limited to adding a "Contents List" which includes my company name and address. The gift pack is featured in the same manner in my catalogue. While some of these products have nutrition labeling, some do not because the manufacturers have a small business exemption and no claims are made. Am I responsible for providing nutrition labeling for the items that do not carry nutrition information?
Answer: Nutrition labeling must be made available for all foods in a gift pack unless the packer, as well as the manufacturer, qualifies for a small business exemption. Section 101.9(h)(3)(i) allows for the added nutrition information to be placed on an insert in the gift pack rather than on each package label.

NUTRITION LABELING OF RESTAURANT FOODS (# 101.10)

R65.

Question: I understand that foods served or sold in restaurants are exempt from nutrition labeling if they do not bear a claim. Once they bear a claim, the restaurant must provide nutrition information upon request for the food that bears the claim. Does a restaurant have to use the Nutrition Facts format to provide nutrition information?
Answer: No. FDA is not requiring full nutrition labeling for restaurant foods, nor is it requiring that nutrition information be presented in the Nutrition Facts format. Because restaurant foods tend to be prepared or sold differently from foods from other sources, FDA has amended # 101.10

to provide a number of flexibilities for restaurants in how they determine the nutrient content of a food (e.g., using data base analysis or other reliable sources of nutrient information) and in how this information may be presented to consumers (e.g., in various formats and by reasonable means, such as in a flier or notebook) (January 6, 1993, 58 FR 2302 at 2410).

R66.

Question: Which foods can take advantage of the flexible provisions of # 101.10 (Nutrition labeling of restaurant foods)?
Answer: Section 101.10 was established to provide flexibility to restaurants and similar establishments when it is the restaurateur who is responsible for determining nutrient content or providing nutrition labeling for foods that are served or sold in such establishments. The nutrition labeling provisions in # 101.10, and discussed herein, also extend to the restaurant-type foods described in # 101.9(j)(3) provided they meet the requirements of that section (i.e., they are: similar to foods served in restaurants, ready-to-eat, not for immediate consumption, and prepared or processed primarily at the retail location from which they are sold).

R67.

Question: Can a commercial food manufacturer use the nutrition labeling provisions of # 101.10 (Nutrition labeling of restaurant foods) for foods that he/she manufactures, packages, and labels for sale or use in restaurants? Would it matter if the food was sold only in restaurants?
Answer: No. Section 101.10 was established to provide flexibility to restaurants and similar establishments when it is the restaurateur, not a manufacturer, who is responsible for determining nutrient content or providing nutrition labeling for food sold in such establishments. Consistent with the agency's treatment of commercially packaged fresh fish and nuts (Q **R50** and **R55**), when a manufacturer or packer labels a packaged food, including foods sold only in restaurants, the nutrition information must be presented according to the requirements in # 101.9 (Nutrition Facts) and would be judged by the compliance criteria of that section. The exception would be foods sold for use in restaurants but not served to consumers in the package in which they are received (e.g., large, institutional size containers) (## 101.9(j)(2)(iv) and (v)). Because such foods are exempt from nutrition labeling requirements, even if they bear a claim, voluntary nutrition labeling may be presented for these foods by any reasonable means, including those provided for in # 101.10.

R68.

Question: Does nutrition information have to appear on the same labeling that bears a nutrient content claim or health claim? For example, would a claim for a food listed on a placard require nutrition information on the placard also?
Answer: No. Section 101.10 requires that nutrition information be available upon request. It may appear on the same or different labeling from that which bears the claim. It may be presented in various forms, including those specified in # 101.45 (e.g., displayed at point of purchase by an appropriate means, such as affixing it to the food, by posting a sign, or by making the information readily available in a brochure, notebook, or leaflet, in close proximity to the foods), Nutrition Facts (# 101.9), and by other reasonable means (# 101.10).

R69.

Question: A restaurant prepares and sells a number of foods that bear a claim, including an ice cream sandwich made with "low fat ice cream." The ice cream sandwich may be served for immediate consumption or it may be wrapped and sold from a self-service cold case in the restaurant. The wrapped sandwiches sold from a self-service case bear a claim on the package label. The restaurant provides consumers, upon request, with a brochure containing nutrient content information, according to # 101.10, for the foods it serves for immediate consumption that bear claims. Can the restaurant use the same brochure to meet nutrition labeling for the wrapped

ice cream sandwich that bears a claim on its label or does it have to put Nutrition Facts on each package? ***Answer:*** Foods that are served or sold in restaurants and similar establishments may bear nutrition information according to # 101.10, even if the food is sold in packaged form and a claim or other nutrition information appears on the package label provided the food is labeled by the restaurateur.

R70.

Question: How may nutrition information be presented for restaurant-type foods that are primarily processed or prepared at the retail location from which they are sold when that location does not have facilities for immediate consumption? Please address salads prepared and sold in-house in your answer.
Answer: Many restaurant-type foods (i.e., ready-to-eat but not for immediate consumption) that are prepared at the same retail location from which they are sold have similar needs for flexible nutrition labeling as foods served or sold by restaurants (e.g., the foods are generally hand assembled and, therefore, subject to individual product variations). Thus, the general provisions of # 101.10 discussed in this section are available to restaurant-type foods that meet the criteria set out in # 101.9(j)(3). For example, if a grocer prepares and sells a "low fat" potato salad in-house, nutrition labeling must, at a minimum, provide information on the fat content of the food. This information would be available to the grocer from his/her reasonable basis determination that the food meets FDA's definition for the claim. Nutrition information for a restaurant-type food that bears a claim must be available to consumers upon request and may be presented by reasonable means (e.g., in a brochure or posted at point of purchase).

R71.

Question: Can a restaurant provide nutrition information to consumers orally, or must it be presented in written form?
Answer: Nutrition information for restaurant and restaurant-type foods may be provided by any reasonable means, including orally. A statement from a waiter, for example, that a "low fat" meal contains less than 10 grams of fat will serve as the functional equivalent of full nutrition labeling. In such a case, however, the restaurant should also have nutrition information in writing, as a back-up, to ensure that the information communicated by the staff is valid.

R72.

Question: I understand that nutrition information for packaged foods must be provided for the food "as packaged." Information for the nutrient values of the food "as prepared" is voluntary and would be listed in a second column. What is the basis for nutrition labeling of a food served in a restaurant (not in packaged form), the uncooked ingredients or the prepared food?
Answer: Nutrition information must be provided on the basis of the food as packaged or purchased by the consumer (# 101.9(b)(9)). Thus, nutrition labeling of a ready-to-eat food served in a restaurant or similar establishment would be based on the nutrient content of a single serving of the finished product as it is marketed for purchase by consumers.

R73.

Question: Which nutrients should a restaurant include in nutrition labeling?
Answer: At a minimum, restaurants must provide information on the nutrient that is the basis for the claim, e.g., "low fat, this meal contains 10 grams of fat."

R74.

Question: How does a restaurant determine which nutrients are the basis for a claim, i.e., which nutrients must be included in nutrition labeling?
Answer: Nutrients that are the basis for a claim include all nutrients that are relevant in

determining whether a food meets the definition for a claim. For example, fat claims are based on the fat content of a food. Thus, nutrition information for a "low fat" food must include information on the level of fat in the food bearing the claim. Cholesterol claims are based on the cholesterol content of the food and are allowed only when a food contains 2 grams or less saturated fat per reference amount (2 grams or less saturated fat per 100 grams of food for meals and main dish products). Thus, nutrition information for a food bearing a cholesterol claim must include information on both the cholesterol and the saturated fat content of the food. Health claims include both the general health claims requirements (i.e., that disqualifying levels not be exceeded) and the nutrient requirements for the specific claim (see Q **R109**). This information (e.g., information about the level of the nutrients that are the basis for the claim) should be readily available to a restaurant from its determination that the food conforms to the definition of a claim. (Definitions for nutrient content claims and requirements for health claims are summarized in attachments B, C, and D of this document.)

R75.

Question: If a restaurant wants to provide information on additional nutrients, e.g., nutrients that are not the basis for a claim, can it do so?
Answer: Yes. While the provision of information on nutrients that are the basis for a claim is the minimum requirement for nutrition labeling of restaurant foods, FDA encourages restaurants to provide consumers with as much information on the nutrient content of the food as possible.

R76.

Question: If a restaurateur chooses to voluntarily provide nutrition labeling for a food that is otherwise exempt, how may this be accomplished?
Answer: Generally, the restaurateur may provide voluntary nutrition information according to the options available to foods that bear a claim, i.e., # 101.9 (Nutrition Facts), # 101.45 (voluntary program for raw fruits, vegetables, and fish), or # 101.10 (reasonable means). For example, a restaurateur may choose to provide nutrient content information in a statement such as "Garden salad with grilled chicken, contains 390 calories, 8 g fat, and 13 mg cholesterol." Because nutrition labeling requirements are triggered by a nutrient content claim, health claim, or other nutrient content information, the food would no longer be exempt from nutrition labeling. However, this information can itself serve as the functional equivalent of nutrition labeling, and no additional labeling would be required.

R77.

Question: Would FDA consider a telephone number to be a reasonable means of providing nutrition information for a food sold in a restaurant or other vending facility and which makes a claim?
Answer: No. Once a food bears a claim, nutrition information must be readily accessible to consumers, e.g., on the label attached to the food or in labeling at point of purchase. Vending machine foods that are sold in packaged form should have required labeling on the product visible to the consumer prior to purchase or be otherwise displayed at point of purchase. With respect to foods prepared or processed by the vending machine (e.g., soup dispensed into a cup), the mandatory information may be displayed on the vending machines.

R78.

Question: Must a restaurant include % Daily Values in its nutrition labeling?
Answer: Not necessarily. Nutrition information may be presented in a variety of formats. However, the agency considers % Daily Values to be very important information and encourages such a declaration whenever practicable. If a restaurant chooses to use the Nutrition Facts format, labeling must contain all information, including % Daily Values, required for the chosen format.

R79.

Question: Can a restaurant present nutrition information in a modified version of the Nutrition Facts format? For example, can nutrition information be presented in a format that resembles the Nutrition Facts but that contains elements that were modified or eliminated compared to the requirements of # 101.9?
Answer: No. As stated in response to Q **R65**, a restaurant may choose to present nutrition information in a variety of formats. FDA would not object to a restaurant food bearing nutrition information according to the different Nutrition Facts formats set out in # 101.9 (e.g., the simplified format, the shortened format, an aggregate display, or a linear display) so long as labeling contains all required elements of the chosen format and it meets the requirements of # 101.10 (i.e., it includes information on the nutrient that is the basis for the claim).

R80.

Question: FDA's requirements for the Nutrition Facts format are fairly specific with respect to type style, type size, and placement. Does the agency have similar requirements for nutrition labeling of restaurant foods? ***Answer:*** It depends on the format used. Nutrition labeling for restaurant foods may be presented in various formats, including Nutrition Facts (# 101.9), following the format established for raw fruit, vegetables, and fish (# 101.45), and by other reasonable means (e.g., a statement such as "low fat, this food contains no more than 3 grams of fat" in a brochure or notebook) (# 101.10). Consistent with its flexible approach towards restaurant food labeling, FDA has not established standardized type size or placement requirements in # 101.10. Labeling that is easily accessible to consumers, that contains all required nutrition information, and that is presented clearly and legibly, would be generally consistent with the "reasonable means" provision of # 101.10.

R81.

Question: Data base analysis indicates that a food contains 277 calories, 464 mg sodium, 39.22 g protein, and 5.81 g fat per serving. Can a restaurant use the same numbers that are generated by data base analysis (or provided in a cookbook or other source of nutrient content information) directly in its nutrition labeling?
Answer: Yes. However, labeling that declares nutrient values in a way that implies an unwarranted degree of accuracy could be misleading. To avoid the impression of unwarranted accuracy, as well as to make nutrition labeling easier for consumers to review and understand, restaurants are strongly encouraged to follow the rounding rules set out in # 101.9(c) (see attachment A). To be consistent with these rules, the above values should be declared as 280 calories, 460 mg sodium, 39 g protein, and 6 g fat.

R82.

Question: If an airline provides passengers with a special meal upon request (e.g., a "low sodium" meal), would this be a claim subject to the NLEA? How can nutrition labeling be accomplished?
Answer: If, in response to a special request, the airline provides a special meal and represents that the food or meal is, for example, "low sodium," "reduced sodium," or "low in fat," the airline is making a nutrient content claim for the food, and the food must meet the definition for the claim. Nutrition information must be provided for the nutrient amounts that are the basis for the claim (e.g., "low fat, this meal contains 10 grams of fat") and may be provided by reasonable means (e.g., on the back of a card wrapped with the meal identifying the meal as a special request or in a binder available from the flight attendants).

R83.

Question: Is a restaurant required to provide information on the amounts of nutrients that are not the basis for a claim? For example, if a food bears a "low fat" claim but the sodium content of the

food exceeds a certain level, does the restaurant need to include sodium in its nutrition labeling?
Answer: FDA encourages restaurants to provide as much nutrition information as possible to consumers. However, the NLEA exempts restaurant foods from the referral and disclosure statements that must appear on the principal display panel of a packaged food if the food bears a claim and it contains a nutrient (i.e., fat, saturated fat, cholesterol, or sodium) at a level greater than the disclosure levels set out in # 101.13(h). Further, FDA's regulations provide that, in a restaurant situation, information on the nutrients that are the basis for the claim may serve as the functional equivalent of full nutrition labeling. Thus, in the above example, information about the fat content of the food bearing a "low fat" claim would serve as the functional equivalent of full nutrition labeling.

R84.

Question: Can a restaurant present nutrition information for an item based on an optional form of serving or preparation? For example, if it serves a grilled chicken breast with the skin attached, can it provide nutrient content information on the basis of the chicken with the skin removed?
Answer: As stated in response to Q **R72**, nutrition information must be presented for a food based on the form in which the food is served or sold to consumers. The restaurant may, however, voluntarily provide a second set of information based on an optional method of preparation or serving, e.g., the chicken breast with skin removed. If a claim is made for a food, and the food or meal only meets the definition of the claim based on an optional method of preparation (e.g., if the food may be prepared, on request, with half the oil normally used), this fact must be clearly communicated to consumers.

R85.

Question: I understand that nutrient content information should be based on the labeled serving size for a food. In a restaurant situation, labeled serving size would be the same as an actual or portioned serving, e.g., the amount of food provided by the restaurant in a single serving. What basis should a restaurant use for nutrition labeling if it has no control over serving size? For example, how should a restaurant declare the nutrient content of items offered in a self-service soup and salad bar?
Answer: Even if it is not the restaurant that portions a food, the restaurant may still have a logical frame of reference for serving size. For example, if a restaurant provides patrons with containers or serving utensils that have a given capacity (e.g., soup bowls, salad dressing ladles) and if it is reasonable to expect that consumers may fill the containers to capacity, the restaurant should base nutrient content information on of the amount of food the container could hold. However, if a food bears a claim, it must meet the definition for the claim based on its reference amount, regardless of labeled serving size (see Q **R146**). Nutrient content information for discrete items available at a self-service salad bar, e.g., muffins, whole fruit, or slices of bread, should be declared on the basis of the number of unit items that is closest to the reference amount for the food (# 101.19(b)(2)(ii)).

R86.

Question: FDA has stated that a restaurant may present nutrition information in a statement such as "contains X amount of a nutrient." Does labeling also need to specify serving size, e.g., does it need to list the weight of the food or meal?
Answer: It depends. FDA encourages restaurants to provide as much nutrition related information as possible, including information on serving size. However, consistent with the agency's flexible approach to nutrition labeling on restaurant foods, FDA will accept labeling that provides nutrition information for a single serving of a food or meal that does not specifically state serving size provided omission of this information does not result in labeling that is false or misleading. For example, if a menu lists the items available in a restaurant followed by a description of the

food or meal and information on the fat and calorie content of the food, consumers could reasonably expect that the nutrient content information is declared on a per serving basis, and they will be able to relate this information to the quantity of food they are served. On the other hand, there may be situations in a restaurant where consumers would not have an appropriate frame of reference for nutrition information unless the serving size used as a basis for the information is specified, for example, when a food is available in more than one serving size (e.g., soup sold by the cup and by the bowl) or when serving size varies (e.g., items from a self-service soup and salad bar where the consumer controls portion size). Furthermore, if nutrition labeling is presented in a format that has requirements for declaring serving size (e.g., Nutrition Facts), nutrition labeling must contain all required elements of the chosen format.

R87.

Question: Should a restaurant provide nutrition information on a "per serving" basis, or can the information be declared by other units or measures, such as "per item" or "per unit?" For example, if a restaurant sells whole pizza and pizza by the slice, how should nutrition information be declared?

Answer: Generally, nutrition information should be presented on a per serving basis. Nutrition information on a per unit basis could be appropriate when a single unit may also be a single serving. However, the basis for the information must be clearly communicated to consumers. It is especially important that the basis be declared when a food is available in more than one size serving, e.g., pizza that is available whole and by the slice, or soup that is available by the cup or by the bowl. The restaurant may provide additional information, such as "8 slices per medium 16-inch pizza, 1 slice contains..." to help consumers put nutrition information in context. Conversely, it would be misleading to present the information on a per item basis when a serving generally contains more than one item of the food, for example, if a single serving of cookies contains more than one cookie.

R88.

Question: Can a restaurant provide nutrition information on a per item basis when the item is significantly larger than FDA's reference amount for the food? For example, the reference amount for muffins is 55 g. If a restaurant serves a muffin that weighs 165 g (three times as big as the reference amount) can it still treat the muffin as a single serving?

Answer: If a unit weighs 200 percent or more of the reference amount set out in # 101.12(b), it may be labeled as a single serving provided it is reasonable to expect that the food would be consumed in a single sitting.

R89.

Question: For packaged foods, the actual amount of naturally occurring vitamins, minerals, and protein must be at least 80 percent of the values that are declared on the label, whereas the actual calorie, carbohydrate, and sodium contents may not exceed the labeled values by more than 20 percent. Will FDA apply these same compliance criteria to the nutrient content information declared on labeling for restaurant foods?

Answer: No. The above compliance criteria (# 101.9(g)) were established to account for natural variations in the nutrient content of commercially manufactured and packaged foods that are subject to chemical analysis to determine compliance. These criteria ensure that values declared in the Nutrition Facts panel for nutrients such as vitamins and minerals are not over-declared, and that nutrients such as calories and fat are not under-declared, compared to actual amounts that are determined by chemical analyses. The standard that restaurant foods must meet is that a restaurateur have a "reasonable basis" for believing a claim or other nutrition information is valid. Thus, FDA will not subject restaurant foods to chemical analysis to determine whether nutrient levels are properly declared. Rather, FDA will be assessing whether the restaurant's basis for a

claim or other nutrition information is, or is not, reasonable. For example, if a restaurant claims a meal is "low fat," FDA would look at the recipe, calculations, and any other information used by the restaurant in determining whether the meal meets the definition of "low fat," i.e., that it contains no more than 3 g fat per 100 g of food.

R90.

Question: Can a restaurant provide nutrition information for different components of a single food or meal separately? For example, can it provide one set of nutrient content information for a salad and a second set of information for the salad dressing if the dressing is served on the side?
Answer: Nutrition information for different components of a food or meal can be presented separately when the components are served separately (e.g., for a sauce or dressing served on the side), or where the components are separate entities, e.g., a steak, baked potato, and green vegetable, even if the components are served together. It could be misleading, however, to present nutrition information separately for mixed components where the consumer could not reasonably be expected to separate them, e.g., if the dressing is served on the salad.

CONTEXT OF CLAIMS AND COVERAGE BY THE NLEA

The Claim

Nutrient content claims:

R91.

Question: What is a nutrient content claim? Could you provide some examples?
Answer: A nutrient content claim is any statement about a food product that directly, or by implication, characterizes the level of a nutrient in the food (# 101.13(b)). Thus, nutrient content claims include direct statements about the level (or range) of a nutrient in a food, e.g., "low sodium," "reduced fat," or "contains 100 calories." An implied nutrient content claim is any claim that: (1) describes the food, or an ingredient in the food, in a manner that suggests that a nutrient is absent or present in a certain amount, e.g., "no tropical oils" or (2) suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices when the claim is made in conjunction with an explicit nutrient content claim, e.g., "healthy, contains 3 grams of fat."

R92.

Question: Would use of terms such as "Nutritious," "Wholesome," "Best choice," or "Good for you" on the label or labeling of a food subject the food to the claims requirements?

U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

March 12, 2004

Counting Calories
Report of the Working Group on Obesity

Table of Contents

I. Introduction

A. Public Health Impetus

The nation is currently facing a major long-term public health crisis. In recent years, unprecedented numbers of Americans of all ages have become either overweight or obese.(2) This trend toward overweight and obesity has accelerated during the past decade and is well documented (see Box 1) by numerous scientific analyses. (For convenience, future use in this document of the term obesity includes both overweight and obesity.) Unfortunately, this trend towards obesity shows no signs of abating. If it is not reversed, the gains in life expectancy and quality of life resulting from modern medicine's advances on disease will erode, and more health-related costs will burden the nation's healthcare systems. For these reasons, the trend toward obesity must be reversed.

Box 1 - Facts and Figures on Overweight and Obesity

The scope of the growing and urgent public health problem of obesity is outlined in the Surgeon General's Call to Action (DHHS, 2001). In 1999-2000, 64% of U.S. adults were overweight, increased from 56% when surveyed in 1988-1994; 30% of adults were obese, increased from 23% in the earlier survey (DHHS, 2003; Flegal *et al.*, 2002). Among children age 6 through 19 years, 15% were overweight, compared with 10 to 11% in the earlier survey (CDC, 2003; Ogden *et al.*, 2002). Overweight and obesity are associated with increased morbidity and mortality. It is estimated that about 400,000 deaths per year may be attributed to obesity, and overweight and obesity increase the risk for coronary heart disease, type 2 diabetes, and certain cancers (Mokdad, *et al.*, 2004). The total economic cost of obesity in the United States is up to $117 billion per year (DHHS, 2003), including more than $50 billion in avoidable medical costs, more than 5 percent of total annual health care expenditures (DHHS, 2001; DHHS, 2003).

The prevalence of overweight and obesity varies by gender, age, socioeconomic status, and race and ethnicity (DHHS, 2001). For example, although overweight has increased among all children, the prevalence of overweight and obesity is significantly higher among non-Hispanic black and Mexican-American adolescents than among non-Hispanic white teens (12-19 years old) (Ogden *et al.*, 2002). A majority of non-Hispanic black women over 40 are overweight or obese (Flegal *et al.*, 2002).

The problem of obesity in America has no single cause. Rather, obesity is the result of multiple factors acting together over time, including genetic (Loos and Bouchard, 2003) and environmental factors (Hill and Peters, 1998; Hill *et al.*, 2003).[3] Similarly, there will be no single solution to the problem of obesity; it will be brought under control only as a result of coordinated, complementary efforts from a variety of sectors of society. The obesity epidemic also will not be solved quickly. Any long-lasting reversal of this phenomenon will itself be a long-term process.

Obesity is associated with significant health problems in the pediatric age group and is an important risk factor associated with adult morbidity and mortality. The causes and mitigation of childhood obesity have been and continue to be the focus of much attention (Hill and Trowbridge, 1998; Barlow and Dietz, 1998; Ashton, 2004; Bowman, *et al.*, 2004). A policy statement of the American Academy of Pediatrics proposes strategies for early identification of excessive weight gain by using BMI,[4] for dietary and physical activity interventions during health supervision encounters, and for advocacy and research (AAP, 2003). According to Ritchey and Olson (1983), parental behavior is a dominant influence on children's eating habits. For adults, the literature discusses how having a specific behavior goal for the prevention of weight gain (e.g., increasing physical activity or eating less at each meal) may be key to arresting the obesity epidemic (Wyatt and Hill, 2002; Hill, 2004). In similar fashion, the *Dietary Guidelines for Americans* includes a chapter on physical activity, linking physical activity with nutrition.

The combined efforts of Federal, state and local governments, the packaged food industry, the restaurant industry (including both quickservice and other types of restaurants), the professional health community (including primary care physicians, nutritionists, dietitians, and others), consumer advocacy groups, schools, the media and, of course, committed individuals will all be required to contribute to the solution to the problem of obesity.

The current crisis has been recognized by many of these groups, including a number of our stakeholders, for some time, and many wide-ranging efforts to address and reverse the trends that lead to obesity are already underway. Within the DHHS, Secretary Tommy G. Thompson has led efforts to address the public health problem of obesity. On July 30, 2003, Secretary Thompson convened a roundtable on obesity/nutrition involving experts from academia, the health professions, industry, and government to consider the role that the Department can play in reducing or reversing the weight gain that leads to obesity (see Appendix C for the five questions presented at the roundtable). DHHS also established a Docket in FDA (Docket No. 2003N-0338)

to gather additional information on this topic.

Each group now working on the problem of obesity brings unique resources and expertise to bear on it. Among the major Federal government entities with a responsibility and a capability to address the problem, FDA, within the broader context of DHHS, is bringing its own unique strengths to bear, including relevant legal authorities.

B. FDA Obesity Working Group

In a memorandum dated August 11, 2003 (see Appendix D for the August 11 memorandum), Commissioner of Food and Drugs Mark B. McClellan, M.D., Ph.D., created the OWG and gave it its charge. FDA Deputy Commissioner Lester M. Crawford, D.V.M., Ph.D., chairs the OWG; the Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN), Robert E. Brackett, Ph.D., is the vice-chair.[5] Other members of the OWG (see Appendix E for list of OWG members) were selected from across FDA to provide expertise and knowledge in a range of relevant scientific and other disciplines. The Commissioner requested that the OWG deliver, in six months, a report that outlines an action plan covering critical dimensions of the obesity problem as outlined in the charge and to help consumers lead healthier lives through better nutrition.

During its tenure, the OWG met eight times; received briefings from several invited experts from other government agencies; held one public meeting, one workshop, two roundtable discussions (one with health professionals/academicians, and one with representatives of consumer groups); and solicited comments on obesity-related issues, directing them to the Docket that DHHS established in July 2003 (Docket No. 2003N-0338). In addition, some members of the OWG met with representatives from various sectors of the packaged food and restaurant industries.

To accomplish its work, the OWG organized several subgroups (see Appendix F for list of OWG subgroups), each designed to focus on a particular aspect of the Commissioner's original charge. In addition, in order to inform its work, the OWG created a knowledge base subgroup. All the subgroups, in turn, met separately and developed respective analyses and recommendations, which serve as the basis for this report. This report presents the OWG's recommendations that are responsive to the Commissioner's charge, and that the OWG believes can contribute to confronting obesity in the United States.

II. Foundations of this Report

Any FDA effort to address obesity must be based on the following: (a) adherence to fundamental scientific principles; (b) conformance with FDA's public health mission and legal authorities; and (c) consideration of consumer and other stakeholder views and needs.

A. Scientific Principles

Fundamentally, obesity represents an imbalance between energy intake (e.g., calorie intake) and energy output (expended both as physical activity and metabolic activity; see text box on Calorie (Energy) Balance at Appendix B). Although there is much discussion about (1) the

appropriate makeup of the diet in terms of relative proportions of macronutrients (fats [lipids], carbohydrates, and protein) that provide calories and (2) the foods that provide these macronutrients, for maintenance of a healthy body weight it is the consumption and expenditure of calories that is most important. In other words, "calories count."(6)

1. Calories

Quite simply, the OWG's recommendations center on the scientific fact that weight control requires caloric balance. Food supplies the energy that provides fuel for the body and for rebuilding the "wear and tear" one is subjected to during the day. The traditional unit for expressing the energy value of foods is the *kilocalorie* (kcal). The term *calorie* is commonly used in place of kilocalorie. One calorie is equal to 4.184 kilojoules (kjoules) a common unit of energy used in the physical sciences and internationally in nutrition labeling. The caloric intake that is appropriate for an individual depends on a number of factors, including height, weight, gender, and age.

2. Calorie Contribution of Macronutrients

Attention to caloric intake is a key element of weight control (the other is caloric expenditure). The three macronutrients that provide energy in our diets are carbohydrate, protein, and fat (see text box on Carbohydrates and Other Macronutrient Contributions to Caloric Value at Appendix B). (Alcohol is also a source of energy, yielding 7 calories per gram, but it is not a nutrient.(7)) These macronutrients yield different amounts of energy in the form of calories per unit weight.

- Carbohydrate = 4 calories per gram
- Protein = 4 calories per gram
- Fat = 9 calories per gram

To maintain a constant bodyweight over time, "energy in" from food must equal "energy out" as a result of resting metabolism plus physical activity. In other words, calories eaten should equal the calories expended on a daily basis. Bodyweight will change if one alters this basic balance. If one consumes even slightly more calories than one expends over time, one will eventually gain weight (Wright, *et al.*, 2004). Conversely, if one consumes fewer calories than one expends over time, one will eventually lose weight.

B. FDA's Public Health Mission and Legal Authorities

FDA's mission is to promote and protect the public health. It seeks to accomplish this mission by enforcing the laws it is charged with administering and by conducting educational and public information programs relating to its responsibilities.

The Federal Food, Drug, and Cosmetic Act (the Act) as amended by the Nutrition Labeling and Education Act of 1990 (NLEA, Public Law 101-535), together with FDA's implementing regulations, established mandatory nutrition labeling for packaged foods to enable consumers to make more informed and healthier food product choices in the context of the total daily diet. The statute and the regulations were also intended to provide incentives to food manufacturers to improve the nutritional quality of their products.

The cornerstone of the NLEA is the Nutrition Facts panel (NFP), which lists the total number of calories derived from any source, as well as the total number of calories derived from total fat. The amounts of total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, and protein in the food are also listed in the NFP, both as the quantitative "amount per serving" (grams or milligrams) and, with the exception of sugars and protein, as the percent of a dietary reference value, called the "percent Daily Value" (%DV). FDA requires the declaration of nutrients as a %DV, in part to help consumers understand the role of individual foods in the context of the total daily diet. Also, to help consumers determine how their individual dietary needs compare with the reference daily values used on the label, the NFP includes a footnote that specifies that the reference daily values are based on a 2,000 calorie diet. On larger packages, the footnote goes on to list the daily values for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber for both a 2,000 and a 2,500 calorie diet.

As part of FDA's regulations implementing the NLEA, the agency established reference amounts customarily consumed (RACCs) for 139 food categories that manufacturers are to use in developing serving sizes that are then expressed in household measures (e.g., teaspoons, cups, pieces). These serving sizes become the basis for reporting the amount of each nutrient present and enable consumers to compare the nutritional qualities of similar food products.

Under the NLEA, FDA also has authority over health claims and nutrient content claims for foods. Appropriate health claims and nutrient content claims, like nutrition labeling, further the statutory objectives of enabling consumers to make more informed and healthier food product choices and encouraging manufacturers to improve the nutritional quality of their products.

A health claim is a claim that characterizes the relationship between a food, or a food component, and a disease or a health-related condition, and may only be made in accordance with an authorizing regulation issued by FDA. An example of a health claim is: "Although many factors affect heart disease; diets low in saturated fat and cholesterol may reduce the risk of heart disease." A nutrient content claim is a claim that characterizes the level of a nutrient in a food, and it, too, must be made in accordance with an authorizing regulation issued by the agency. Nutrient content claims describe the level of a nutrient or dietary substance in the product, using terms such as "free," "high," and "low," or they compare the level of a nutrient in a food to that of another food, using terms such as "more," "reduced," and "lite." More information on FDA's implementation of these authorities can be found at http://www.cfsan.fda.gov/~dms/hclaims.html.

Restaurants, unlike the manufacturers of packaged foods, are not required by the NLEA to provide nutrition information for a menu item or meal unless a nutrient content claim or a health claim is made for such item or meal. When such a claim is made, the restaurant need only provide information on the amount of the nutrient that is the basis of the claim. Thus, for example, if a restaurant claims that a particular menu item is "low in fat" (i.e., makes a nutrient content claim with regard to fat) then this requirement is satisfied by adding: "low fat - provides fewer than 3 grams fat per serving" (i.e., the basis of the "low fat" claim). The restaurant may provide information about the nutrient for which the claim is made in various ways, including in brochures. In other words, restaurants need not provide such information on the menu or menu board.

A restaurant making such a claim also would not be required to provide complete nutrition information; its decision to provide nutrient content information about one nutrient does not

trigger a requirement to disclose complete nutrition information for that item or meal.

C. Stakeholder Participation

From the outset, FDA asked stakeholders to identify obesity issues that FDA should address. Prior to the creation of the OWG, DHHS convened a round table discussion in late July 2003 (bringing together experts from academia, the health professions, industry, and government) to consider how best to address the obesity issue, as reflected in five questions presented to the round table for discussion (see Appendix C for the five questions). As noted above, DHHS also established a Docket in FDA (Docket No. 2003N-0338) to gather information on this subject.

Following the creation of the OWG, FDA provided several opportunities for stakeholder participation: a public meeting on October 23, 2003; a workshop on November 20, 2003, that was co-sponsored and funded by the DHHS Office of the Assistant Secretary for Planning and Evaluation (OASPE); roundtable meetings with health professionals/academicians and consumer groups respectively, on December 15 and 16, 2003; and meetings with representatives of the packaged food and restaurant industries. FDA used these opportunities to solicit public comments on the obesity issue, as reflected in six questions the agency asked (these questions are set out in section VI.A. of this report). FDA used the Docket established in July 2003 (Docket No. 2003N-0338) to gather additional comments; the OWG organized the comments to this docket into a searchable database that informed preparation of this report.

D. The OWG's Work

The remainder of this report reflects the work of the OWG subgroups:

- ***Obesity Knowledge Base:*** Gathered information on existing obesity, weight management, and nutrition related programs.
- ***Messages:*** Identified existing obesity-related messages in the public and private sectors; conducted focus groups to test five messages; recommended a calorie focus for FDA's action plan.
- ***Education:*** Explored and is initiating a number of new and enhanced private and public sector partnerships to focus on obesity education.
- ***Food Label:*** Explored options for enhancing the food label in relation to efforts to address obesity.
- ***Restaurants/Industry:*** Explored options for providing consumers with nutrition information on food consumed outside the home; considered the potential health consequences of using diet plans and related products.
- ***Therapeutics:*** Surveyed existing therapies for mitigating obesity; recommended next steps for updating the 1996 draft guidance entitled "Guidance for the Clinical Evaluation of Weight-Control Drugs."
- ***Research:*** Identified gaps in obesity knowledge and areas for further biomedical and social sciences research.
- ***Stakeholder Investment:*** Held meetings and a workshop to solicit stakeholder views; and organized the comments to Docket No. 2003N-0338 into a searchable database that informed preparation of this report.

III. Messages

The Commissioner charged the OWG to set out specific means for developing and implementing a "clear, coherent, and effective FDA message (within the broader context of DHHS) that will unify various public and private efforts to reverse the current obesity epidemic." This part of the charge was expanded with an eye toward establishing a broader theme that focuses on calories[8] as a fulcrum for further action, in the context of an overall healthful diet as defined by the DHHS/USDA *Dietary Guidelines for Americans.*

A. Obesity Knowledge Base

Prior to considering obesity messages and to ensure that it was aware of the range of current public and private efforts to address obesity, the OWG formed a subgroup to collect information on existing and planned obesity-related activities in the United States; assemble a centralized repository of the information gathered; and report out to the full OWG on the scope/contents of the repository.

A majority of the activities listed in the repository and database are programs that provide advice on nutrition/diet and/or physical activity. Most associations, agencies, and organizations identified are sending out the message that diet and physical activity should be addressed together in the fight against obesity.

Many partnerships or collaborations exist between government agencies and/or private entities. There are several areas, however, where different groups manage similar programs. These similar programs, if merged into a larger partnership, could have a greater impact.

To determine whether various programs, activities and initiatives are effective in reducing and/or preventing overweight and obesity in the United States, program evaluation must improve. In addition, improvements are needed in educational outreach to convey the messages and implement the initiatives that government and non-government entities have developed.

B. Obesity Messages

Message Recommendation Highlight:

- ***Develop messages tied to a "calories count" focus***

The OWG formed a subgroup to identify existing messages in the public and private sectors and to set out specific means for developing simple, clear, coherent, and effective FDA messages around the theme of "calories count" based on the scientific fact that net calorie gain or loss over time is the root cause of obesity.

1. Identifying Existing Messages

Today, consumers are inundated with a range of messages about food. Some of these messages are in the form of food advertisements or marketing efforts that focus on product convenience,

taste and value. Other messages relate to weight-loss programs or products, or weight management. Some of the messages in each of these areas may not necessarily direct consumers toward wise dietary choices.

The Federal government tries to provide long-term sound nutrition advice to consumers (e.g., government-sponsored public health campaigns). For example, DHHS collaborates with the USDA to establish and promote the *Dietary Guidelines for Americans,* which provide guidance on choosing a lifestyle that combines sensible eating with regular physical activity. An important recent effort of DHHS is *Steps to a HealthierUS.*[9] In support of the President's *HealthierUS*[10] initiative, the DHHS effort emphasizes personal responsibility for the choices Americans make to ensure that policy makers support prevention programs that foster healthy behaviors.

2. FDA Focus Groups on Obesity Messages

Box 2 - FDA Focus Groups

FDA conducts its own consumer research to evaluate the appropriateness and effectiveness of its messages. For example, FDA conducted consumer research before the implementation of NLEA, to determine the usefulness of potential choices for the NFP format. Since NLEA, FDA and other researchers have studied how consumers use the NFP, nutrient content claims, and health claims (separately and in combination) to make dietary choices.

Consumer research is used to assess people's knowledge, attitudes, perceptions, and preferences for a topical subject area or reactions to any type of stimuli. Research methods may include qualitative studies, such as focus groups; quantitative, nationally representative surveys, using structured questionnaires; experimental studies of consumer responses to labeling and package variations; and intervention studies of the effects of point of purchase labeling.

In November-December 2003, FDA, with OASPE funding, conducted focus group research. There were 8 groups of 7-10 participants. Groups were segregated by gender and education level. All participants were at least 18 years old, had been grocery shopping and had eaten in a fast food and/or quickservice restaurant in the past month. The purpose of the groups was to explore (1) how consumers use the nutrition information on food labels; (2) what type of nutrition information they would like to see in quickservice restaurants; and (3) which messages would be effective as part of a public information and education effort aimed toward encouraging consumers to use the food label. Participants discussed and reacted to variations in the NFP and the principal display panel (PDP) on food packages and to various presentations

of nutrition information at restaurants.

It is important to emphasize that the findings from these focus groups are based on qualitative research with small sample sizes. They should not be viewed as nationally representative or projectable. Quantitative experimental data are necessary to make reliable and verifiable conclusions. However, these focus group results shed some interesting light on the complex issues discussed in this report and are useful in identifying quantitative research needs.

The focus group findings discussed in this report are preliminary and are based on observations recorded by the observer, as well as post-group discussions with the focus group moderator and other observers.

In November and December 2003, FDA focus groups were convened to evaluate, among other things: (1) how consumers use the nutrition information on food labels; and (2) which messages would be effective as part of a public information and education effort aimed toward encouraging consumers to use the food label (see Appendix G for FDA Division of Market Studies report, referenced in this report as FDA, 2003).[11] Appendix H contains a discussion on the development of effective consumer messages. The findings from the FDA focus group efforts are discussed below.

FDA developed five NFP-based messages that the agency tested through its focus groups. The messages and materials were intended to remind people where to find the NFP, why it is there, and how to use the information; while at the same time reinforcing various "promises" (i.e., motivators) associated with regularly using the NFP.

The messages tested were as follows:

1. "Read it before you eat it - Always look at the Nutrition Facts"
2. "Calories count and fat matters - Always look at the Nutrition Facts"
3. "Do you know the serving size? - Always look at the Nutrition Facts"
4. "What you eat is what you are - Always look at the Nutrition Facts"
5. "If you read labels for things you put *on* your body, why wouldn't you read labels for what you put *in* your body?"

Overall, none of these "slogan-type" messages resonated particularly well with the FDA focus group participants. Nevertheless, FDA focus group participants believed that reminder messaging about the NFP would be helpful. In addition, the results of other focus groups indicate that messaging should emphasize small, incremental steps versus major life changes with respect to weight management and obesity prevention, and should address the importance of "planning ahead" as a necessary step for eating right (Borra *et al.*, 2003; IFIC, 2003).

C. OWG Message Recommendations

The OWG recognizes that some focus group (Borra *et al.*, 2003; FDA, 2003; IFIC, 2003) and some quantitative data (Derby and Levy, 2000; Levy, 2004; Lin, 2004) indicate that not all consumers pay enough attention to calorie information in the NFP. Nevertheless, given the fact that obesity, at its most fundamental level, is a direct function of caloric imbalance, the OWG believes that "calories count" must be the focus for its recommendations. Accordingly, in relation to messages, the OWG recommends the development and testing of messages tied to this focus.

IV. Education Program to Deliver the Message

Education Recommendation Highlight:

- ***Establish partnerships to educate Americans about obesity and leading healthier lives through better nutrition.***

The Commissioner directed the OWG to outline an FDA program (component of DHHS program) for educating Americans about obesity and the means to prevent chronic diseases associated with it.

A. Need for Education Programs

Consumer perceptions regarding weight and dietary habits are significant in the fight against the obesity epidemic. Consumers who are not aware of their own weight status and its medical implications are unlikely to be receptive to public health efforts to alleviate obesity. This point extends to parental perceptions of children's weight status and dietary habits as well, given that parents have significant influence over their children's environment, habits, and health. Lack of knowledge about weight status and its health implications undermine consumers' "promise" or motivation, a key component of messaging; therefore the OWG identified education as a critical adjunct to effective messaging about caloric balance.

Recent focus group studies conducted by the International Food Information Council (IFIC)[12] suggest that consumers distinguish between "overweight" and "obesity," and consider the first to be of relatively little health significance (IFIC, 2003). Therefore, consumers who consider themselves to be merely "overweight" may have less incentive to take action. There is also evidence to suggest that both adults (Kuchler and Variyam, 2003) and teenagers (Kant, 2002) misperceive their weight status, although the form of misperception can vary with gender, socioeconomic status, age and race and ethnicity. For example, men were found to be more likely than women to underestimate the level of their weight status; healthy or underweight women were more likely to consider themselves overweight. Lower income and education were also associated with underassessment of weight status; higher income and education levels were linked to overestimation of weight status. Parents also appear prone to misjudge their children's weight status and its health significance (Borra *et al.*, 2003; Contento *et al.*, 2003; Maynard *et al.*, 2003). Many parents with overweight children consider their children to be at a healthy weight. In some cases this may be due to cultural perceptions of appropriate weight (Bruss *et*

al., 2003; Contento *et al.*, 2003). In some cases where parents do accurately judge their children's weight status, they may believe that the child will outgrow their overweight or obese status and, therefore, be less likely to take action.

Consumers may have difficulty accurately assessing the nutritional quality of their diet. Although consumers report in focus group studies that they understand what comprises a healthy diet (IFIC, 2003), approximately 40 percent of one sample (almost 3000 household meal preparers drawn from USDA 1994-1996 Continuing Survey of Food Intakes by Individuals (CSFII) data) perceived the quality of their diets to be better than the calculated diet quality (Variyam *et al.*, 2001). Parents, in particular, do not always have a clear picture of their children's diets. In a recent series of focus groups and phone/Internet surveys conducted by the American Dietetic Association Foundation (Moag-Stahlberg *et al.*, 2003), parents significantly underestimated the frequency with which children ate outside of regular mealtimes, such as after dinner and while engaged in sedentary activities like television viewing. A recent report by the Kaiser Family Foundation discusses the role of media in childhood obesity (KFF, 2004).

Qualitative research by Borra and colleagues (Borra *et al.*, 2003) also suggests that children (aged 8-12 years) give little thought to good health, although they associate achieving "good health" with what they eat, rather than with physical activity. For many of the children involved in the research by Borra and colleagues, the term "healthy" had negative connotations; for example, it meant having to eat fruits and vegetables they did not like or not eating their favorite foods. In terms of weight, children between 8 and 10, regardless of their own weight, did not think about food choices. Equally disturbing, some 11-12 year olds who were overweight said they tried to lose weight by skipping meals, rather than by eating differently. Among a group of children perceived to be above normal weight for their age, Borra and colleagues found that although the children knew it was important to eat healthfully because their parents stressed it at home and they learned about nutrition in school, this teaching provided little useful information for the children.

These qualitative findings are supported by a recent unpublished survey conducted for the nonprofit Dole Nutrition Institute of more than 6,000 children between grades 1-8 in 194 classrooms (Dole, 2003). The responses to survey questions "What is obesity?" and "Which statement is true [about being overweight]?" indicate that many children seem to have either misperceptions or are misinformed about (1) the meaning of obesity and (2) the value of exercise in preventing or mitigating health problems due to overweight.

B. OWG Education Recommendations

The OWG recommends that FDA focus its education strategy on influencing behavior, as well as imparting knowledge, in the context of healthy choices for consumers. Any such efforts will require a long-term agency commitment. Education programs should help consumers make more informed food choices that result in better weight management; should direct messages to large audiences on a frequent basis; and should be crafted to reach a variety of audiences.

The OWG recommends that FDA implement education programs incrementally and design them to be flexible enough to take into account new research findings and policy decisions and possible changes in the food label (e.g., revisions to the content or format of the NFP). Education efforts, however, should not be delayed pending such changes. Education programs

should be simple to understand and apply, and should focus on showing consumers how to achieve a specific goal.

Given the resources and time that FDA would need to develop and implement new education programs for multiple subpopulations, the OWG recommends that FDA, as part of a larger DHHS initiative, establish relationships with private and public sector partners for educational outreach. Such efforts will have the ability to reach larger and more diverse audiences on a more frequent basis, and will enable calorie-focused education campaigns to begin more quickly. Given the prevalence of obesity among children, establishing relationships with youth oriented organizations is especially important. For this reason, the following partnerships are being pursued as a part of a larger DHHS initiative:

- **Girl Scouts of the USA :** FDA and Girl Scouts of the USA seek to launch an initiative entitled "Healthy Living." Building on current Girl Scout resources and programs, the initiative will provide girls and their families with the skills, knowledge, and support needed to make healthier food choices, engage in physical activity, build self-esteem, and maintain a healthier lifestyle. This initiative includes developing a charm of the food label as a part of the Studio B teen collection.
- **National Association of State Universities and Land Grant Colleges (4-H program):** Youth health and obesity is one of three strategic priorities for 4-H Youth Development. FDA envisions a partnership that will use 4-H for targeted population evaluation of obesity/nutrition message(s), and use the 4-H network of over 3,500 professional Cooperative Extension programs across the United States for education and delivery of the message(s).

In addition, FDA, along with other components of DHHS, is participating in the "Shaping America's Youth" initiative to identify actions being taken to address childhood and adolescent inactivity and excess weight. Information collected for this initiative in an on-line survey will be used by "Shaping America's Youth" to prepare a report that provides an overview of current public and private programs that target physical activity and nutrition in our nation's children. As of the date of this report, Shaping America's Youth has registered over 1950 programs directed at the childhood obesity issue, collected surveys of funding and tactical information from over 1150 organizations and entities, and assembled nearly 800 fully completed in-depth surveys from programs representing all 50 states and the District of Columbia.

Public sector partnerships should have the goal of developing programs similar to the "Power of Choice" program FDA developed with the USDA, which teaches children who are 11-13 years of age how to make smart food and physical activity choices in real-life settings. Learning how to use the NFP to make healthy food decisions is a major skill throughout the "Power of Choice" program (see Appendix I for additional information about "Power of Choice"). One way to help better ensure collaboration and cooperation with our public health partners is for FDA to coordinate its messages and educational material with those of its partners.

- **Centers for Disease Control and Prevention:** FDA is pursuing a collaboration between the agency and the CDC to develop a holistic approach to healthy living for children that will enable the FDA to meld a caloric intake message with a CDC caloric output message on physical activity.
- **Department of Education:** FDA has made preliminary contact with the Department of Education to join in supporting programs that target school-age children.

- **Department of Agriculture:** FDA plans to work through DHHS with counterparts at USDA to ensure that the agency's focus on calories is considered as USDA revises its Food Stamp Program/WIC (Women, Infants, and Children) programs and its Food Guide Pyramid, and as DHHS and USDA collectively revise the *Dietary Guidelines for Americans.*

The OWG recommends that FDA work through a facilitator to establish a forum for stakeholders to seek consensus-based solutions to specific aspects of the obesity epidemic in the United States, with a particular focus on the needs of children. As a first step, the OWG further recommends that the initiation of such a dialogue be raised at the next meeting of the FDA Science Board.

V. Supporting the Message

It is important to support any message(s) through appropriate actions and policies where the "calories count" focus is likely to have an impact on consumer knowledge, behavior, and/or treatment (i.e., food labels, restaurants, therapeutics, and research).

A. Food Labels

Food Labeling Recommendation Highlights:

- ***Calories:***
  - ***Issue an ANPRM to solicit public comment on how to give more prominence to calories on the food label.***
  - ***Consider authorizing a health claim on "reduced" or "low" calorie foods.***
  - ***Issue an ANPRM about serving sizes.***
- ***Serving Sizes:***
  - ***Encourage manufacturers immediately to take advantage of the flexibility in current regulations on serving sizes and label as a single-serving those food packages where the entire contents can reasonably be consumed at a single-eating occasion.***
  - ***Highlight enforcement of serving sizes in FDA's food labeling compliance program and consider enforcement action against products that declare inaccurate serving sizes.***
- ***Carbohydrates:***
  - ***File petitions and publish a proposed rule to provide for nutrient content claims related to carbohydrate content of foods, including guidance for use of the term "net" in relation to the carbohydrate content of foods.***
- ***Comparative Labeling Statements:***
  - ***Encourage manufacturers to use appropriate comparative labeling statements that make it easier for consumers to***

> ***make healthy substitutions, including calories (e.g., "instead of cherry pie, try our delicious low fat cherry yogurt - 29 percent fewer calories and 86 percent less fat").***

The Commissioner directed the OWG to "develop an approach for enhancing and improving the food label to assist consumers in preventing weight gain and reducing obesity."

1. The Food Label

The Act, as amended by the NLEA, and FDA's implementing regulations require an NFP on the label of most packaged foods. The NFP lists the serving size, the number of servings per container, the number of calories per serving and the amount and %DV[13] per serving for specified nutrients.

Before recommending any changes in the NFP relevant to obesity, it is important to understand how consumers currently use the NFP and to assess whether the NFP has been effective in facilitating positive dietary change. Research shows that most consumers are familiar with the nutrition information on food labels (Marietta *et al.*, 1999; Neuhouser *et al.*, 1999; Kristal *et al.*, 2001; FDA, 2003), which they use primarily for evaluating the nutrition quality of specific food products, but the percentage of consumers who use NFP information productively for weight management purposes is low (Barone *et al.*, 1996; FMI, 1996; Ford *et al.*, 1996; Levy *et al.*, 1996; Mitra *et al.*, 1999; Roe *et al.*, 1999; Garretson and Burton, 2000; Levy *et al.*, 2000; IOM, 2003; FDA, 2003) (e.g., see Table 1 below).

Table 1. Recent Trends in Reported Food Label Use: 1994-2002 HDS Surveys (Derby and Levy, 2000; Levy, 2004; Lin, 2004)

	1994	**1995**	**2002**
Sample size (N)	**(1,945)**	**(1,001)**	**(2,743)**
	% population (weighted)	**% population (weighted)**	**% population (weighted)**
(1) Percent who use food labels "often" or "sometimes" when buying a food product for the first time			
How often do you read the food label?	70	69	69
(2) Percent who use labels "often" for specific purposes[1]			
To figure out how much to eat	34	40	35
To see if food is high or low in calories, salt, vitamins, fat, etc.	77	83	67

To help in meal planning	34	36	32
(3) Percent who use specific label information "often"[2]			
Do you use the serving size information, when available?	29	26	Not Asked

[1] Based only on label users who "often" or "sometimes" use labels when they buy a food product for the first time.

[2]Based on all respondents.

Associations between dietary behavior and food label use have also been identified, although the body of literature is relatively small (IOM, 2003). A low-fat diet, for example, has been positively correlated with food label use, both in the general population and among family clinic patients. Clinic patients with health conditions (e.g., high blood pressure or high cholesterol) as well as consumers who are in action or maintenance stages of dietary change were also more likely to use the food label (Kreuter *et al.*, 1997; Marietta *et al.*, 1999; Neuhouser *et al.*, 1999; Kristal *et al.*, 2001). In addition, label claims (e.g., low sodium and low fat) may allow consumers to avoid specific ingredients or make food substitutions (Balasubramanian and Cole, 2002), resulting in changes to dietary patterns. Kim and coworkers (Kim *et al.*, 2001) analyzed data from the USDA's CSFII and the Diet and Health Knowledge Survey. Their findings indicate that food label use is positively correlated with measurable increases in the Healthy Eating Index (Kim *et al.*, 2001).(14)

Despite reports of a positive correlation between label use and certain positive dietary characteristics, the trend toward obesity has accelerated over the past decade. It may be that consumers do not take advantage of the available information on the food label to control their weight, perhaps because they do not appreciate how the information could be used for weight management purposes or perhaps because they find it too hard to apply the available information to such purposes. In any case, it is clear that consumers would benefit if they were to pay more attention to and make better use of information, including calories, on food labels. Providing encouragement and making it as easy as possible for consumers to do so are worthy public health objectives.

2. FDA Focus Groups on Food Labels

As described in Box 2, FDA recently conducted focus group research in which it asked general nutrition questions as well as how consumers use the nutrition information on food labels.

The questions covered under general nutrition dealt with three topics: (1) attitudes towards nutrition; (2) macronutrients; and (3) %DV. Those covered under food label modification dealt with six topics: (1) large package sizes; (2) serving versus package; (3) calorie-related variations; (4) serving size variations; (5) calorie cues; and (6) "healthier" symbol. For additional information on FDA's focus group findings, see Appendix G.

Attitudes towards nutrition. In many of the groups, especially the women's groups, participants cared about nutrition and report using the NFP. At the same time, however, many also said that

they do not always consider nutrition when deciding what to eat. Taste, convenience, price, what kind of mood they are in, and what their family eats were often at odds with healthy eating. Although participants were interested in calories, many pointed to multiple concerns that went beyond calories such as the level of saturated fat, total fat, cholesterol, carbohydrates and sodium. Many participants reported not wanting to spend a lot of time reading labels.

Macronutrients. In general, individual participants tended to care more about some macronutrients than others, depending on their individual dietary practices. In most groups, at least one participant was familiar with the Atkins diet and many of these participants were most concerned about carbohydrates and sugars. Others were concerned about fat and saturated fat. Some participants checked the NFP mostly for information about sodium. Those who were on the Weight Watchers diet were concerned about calories and fiber.

%DV. Very few participants reported using the %DV column on the NFP. Either they did not understand the meaning of %DV or they thought that it was not relevant to them since they did not consume a 2000 calorie diet. Those who did use or might use %DV thought that is was a good way to estimate how much of a particular nutrient they were eating or to gauge a healthy and balanced diet.

Large package sizes. In all the groups, participants were presented with a mock-up label of a 20 ounce soda and a large packaged muffin. Both of these products are thought to be commonly consumed in one sitting, but have more than one serving listed.

Serving versus package. In general, participants thought it was misleading to list either product as having more than one serving. Many participants did realize that if the entire package is eaten, the number of servings should be multiplied by the amount of the nutrient of interest, though some participants were confused and made mistakes when trying to calculate the total amount in their heads.

Calorie-related variations. The first test label added a %DV for calories, removed the *calories from fat* line, enlarged the calories line, and changed the way serving size was declared. In general these changes were not noticed by participants. When the new wording for serving size was pointed out, most participants did not think it was an improvement over the existing language.

Serving size variations. The second test label had two %DV columns on the NFP, one for a specified serving size and one for the entire package. In the first four groups, the absolute quantities of macronutrients were only listed for the specified serving size. After comments from these groups, the label was modified to have the absolute amount for both the specified serving size and the entire product. Participants reacted positively to this modification, but some thought it was not necessary to list the amount for a specified serving size.

Calorie cues. Both a "starburst" with the calories per serving and a white square with calories per whole product on the package's PDP were tested. Many participants thought that the starburst was misleading because they thought the manufacturer was trying to indicate the entire product had fewer calories than it did. The white square with the total calories per product got mixed reactions, but many participants just said that they recognized these as high calorie products and would stay away from them.

"Healthier" symbol. Half of the groups tested a "healthy" meat lasagna with a purple keyhole symbol on the PDP. There was generally positive reaction to including a front-of-package symbol indicating that a product was "healthy," as long as participants understood the definition of the symbol and could trust that it was true. Participants believed that they would have to be educated as to the meaning of such a symbol. Some participants mentioned that they would look for the symbol when they were in a hurry in the store. They expressed some concern that these products would cost more or that they would lack in taste.

3. OWG Food Label Recommendations

The OWG recommends that FDA (1) develop options for revising or adding caloric and other nutritional information on food packaging (examples provided below); (2) obtain information on the effectiveness of these options in affecting consumer understanding and behavior relevant to caloric intake; and (3) evaluate this information to make evidence-based decisions on which option(s) to pursue.

a. Calories and Serving Sizes

In light of the critical importance of caloric balance in relation to overweight and obesity, the OWG recommends that FDA: (1) solicit comment on how to give more prominence to calories on the food label; (2) consider authorizing a health claim on "reduced" or "low" calorie foods; and (3) reexamine the agency's regulations about serving size.

Solicit comments on how to give more prominence to calories on the food label. Many of the written and public comments submitted to the agency suggested that FDA develop ways to emphasize calories on the food label. To address this, the OWG recommends that FDA publish an ANPRM requesting comments on how best to give more prominence to calories. Possible changes to the NFP include: (1) increasing the font size for calories; (2) providing for a %DV for calories; (3) eliminating "calories from fat" listing as this takes the emphasis away from "total calories;" and (4) increasing the font size for serving size in order to give it more prominence.

Consider authorizing a health claim on "reduced" or "low" calorie foods. A number of comments submitted to the agency, including those from the FTC, suggested that FDA permit health claims on reduced calorie foods as a way to reduce the risk of certain chronic diseases associated with obesity, such as diabetes, coronary heart disease and cancer. To address this suggestion, the OWG recommends that FDA publish an ANPRM on whether to allow a health claim such as "Diets low in calories may reduce the risk of obesity, which is associated with diabetes, heart disease, and certain cancers" on certain foods that meet FDA's definition of "reduced" or "low" calorie. In addition, the OWG recommends that FDA encourage manufacturers to use dietary guidance statements (e.g., "to manage your weight, balance the calories you eat with your physical activity; have a carrot, not the carrot cake; and as a snack have an apple rather than a serving of potato chips").

Reexamine the agency's regulations on serving sizes. The comments that FDA has received at its public meetings and to the docket (including comments from the FTC) express concern about the serving sizes used in nutrition labeling, particularly on packaged products that can readily be consumed at one occasion but that indicate they represent more than one serving. To

address this issue, the OWG recommends the following:

- In the short-term, that FDA encourage manufacturers immediately to take advantage of the flexibility in current regulations on serving sizes (21 CFR 101.9(b)(6)) that allows food packages to be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single-eating occasion.
- In the long-term, that FDA develop two separate ANPRMs. The first would solicit comment on whether to require additional columns within the nutrition label to list the quantitative amounts and %DV of the entire package on those products and package sizes that can reasonably be consumed at one eating occasion or, alternatively, declare the whole package as a single serving. This ANPRM would also solicit information on products and package sizes that can reasonably be consumed at one eating occasion. The second ANPRM would solicit comments on which, if any, RACCs of food categories appear to have changed the most over the past decade and therefore need to be updated.

The serving size is critical to nutrition labeling since all of the information on nutrient levels depends on the amount of the product represented. By statute, the serving size is to be based on the "amount [of the food] customarily consumed" (section 403 of the Act). Accordingly, when implementing NLEA, FDA reviewed food consumption data obtained from USDA's 1977-78 and 1987-88 Nationwide Food Consumption Surveys and, based on the results of that review, established RACCs for 139 food categories (58 FR 2229, January 6, 1993). Inasmuch as there is evidence that Americans are eating larger portions than they did in the 1970s and 1980s, the OWG recommends that FDA determine whether and, if so, how to update RACCs.

The accuracy of the information in the NFP is crucial for consumers who use this information to monitor their intake of calories and nutrients. Current enforcement efforts targeted at the NFP as described in FDA's Food Labeling Compliance Program[15] are directed at ensuring that actual nutrient levels are within 20% of declared values. More limited resources have been directed at ensuring that serving sizes are calculated and declared accurately. Comments and other information submitted to FDA express concern about the inaccuracy of serving size declarations used in nutrition labeling and reiterate the importance of accurate serving size declarations because all of the information on nutrient levels is dependent upon the amount of the product represented. To address this issue, the OWG recommends that FDA highlight enforcement of serving sizes in the Food Labeling Compliance Program by April 2004, and consider enforcement activities against those products that declare inaccurate serving sizes.

b. Carbohydrate[16] Labeling

Today there is increasing interest in low carbohydrate diets (see text box on Carbohydrates and Other Macronutrient Contributions to Caloric Value in Appendix B). FDA has recently received petitions requesting that the agency provide for nutrient content claims related to the carbohydrate content of foods. Claims for carbohydrate content of foods have become increasingly common in the marketplace while, at the same time, the level of carbohydrates in foods marketed under the various carbohydrate claims appears to vary widely. In order to ensure that terms are consistently defined and that carbohydrate claims are not false or misleading, the OWG recommends that FDA file these petitions and publish a proposed rule to provide for nutrient content claims related to the carbohydrate content of foods, including guidance for the use of the term "net" in relation to carbohydrate content of foods.

c. Other Labeling Issues

The OWG considered comments from the FTC on the issues of (1) reduced/fewer calorie comparisons, (2) comparison to food of different portion size, (3) comparison to food of different product type, and (4) disclosure requirements for comparative claims.

Reduced/fewer calorie comparisons. The underlying principle for FDA's regulation is that reductions be **significant** compared to the reference food (21 CFR 101.60(b)(4). FDA determined that percentage reductions less than 25% were too small to be meaningful because of normal product variability. Such variability may be caused by factors such as: natural nutrient variability of the food due to season of the year, soil type, variety, and weather conditions; variability in processing; rounding rules (e.g., rounding to the nearest 5 calories up to 50 calories and to the nearest 10 calories above 50 calories); analytical variance (ranging from +/- 3-4% to +/- 30 % with an average variance of about +/- 15%); sampling procedures; and shelf life and stability of nutrients in the product.

As a result, 21 CFR 101.9(g) allows for a 20% excess in the actual (analytical) nutrient content of calories, sugars, total fat, saturated fat, cholesterol or sodium of a product compared to the declared nutrient values for that product (and consequently the qualifying values for nutrient content claims) before the food is considered to be misbranded. Therefore, nutrient reductions less than 25% are virtually within the allowable product variability and are not considered significant. The minimum absolute reduction (e.g., equivalent to the value of "low") was changed to permit claims compared to reference foods that were not already "low" in the nutrient because it was the agency's conclusion that benefits derived from several servings of nutritionally modified nutrient dense foods over a day could have a significant impact provided that the reduction was significant, i.e., 25 % or more. FDA further concluded foods already "low" in that nutrient were below the level at which the amount of nutrient in the food becomes significant relative to the total diet and therefore should not be used as reference foods.

For relative claims, the OWG notes that the Codex Alimentarius Commission[17] requires that there be a difference of at least 25% in energy value or nutrient content (except for micronutrients where a 10% difference in the nutrient reference value would be acceptable) with a minimum difference between the compared foods equivalent to a "low" value (FDA's proposed requirements for "less"). Moreover, Canada requires that comparative claims be based on differences which are both nutritionally and analytically significant.[18] Canadian regulations consider reductions of less than 25% from the reference value to be of questionable nutritional significance. Canada does not allow claims on reductions of less than 25%.

The OWG recommends the agency be receptive to such a claim, if the proponent of such a claim is able to provide data and information to substantiate that:

1. The claim is not misleading due to the known variations in food composition and analytical methods, and
2. The claimed reductions are nutritionally significant.

Comparison to food of different portion size. FTC has suggested that FDA consider "allowing food marketers to make truthful non-misleading label claims comparing foods of different portion sizes." FTC provided the example of a 10 oz chicken and rice casserole labeled as

having 33 percent fewer calories than 15 oz. of the same chicken and rice casserole.

Consuming a smaller portion size of the same food simply decreases caloric consumption proportionally. To enable consumers to make meaningful comparisons for calorie reduction, FDA requires such claims to be based on the amount per RACCs, or per 100 gram in the case of meal-type products. Thus, under FDA's current regulations (21 CFR 101.60(b)), a comparative calorie claim of the type that FTC proposes would not be allowed.

Nevertheless, using the food label to promote consumption of smaller portions may have merit. This is especially true if consumers understand that (a) the calorie reduction is solely a function of the reduction in portion size, and (b) that the smaller portion size is actually less than what they usually consume. Thus, the OWG recommends that FDA issue an ANPRM to solicit comments on truthful non-misleading and useful approaches for promoting consumption of smaller portion sizes, including FTC's suggestion.

Comparison to food of different product type (which the OWG refers to as comparative labeling statements). FTC suggests that FDA "consider allowing food companies to make label claims that compare the calories of foods [across] different product categories." FTC points out that switching from one category to another category often can be an effective means of reducing calories, such as substituting carrot sticks for potato chips or fruit for cookies. FTC notes that comparative caloric claims across categories could help consumers make these healthy substitutions. FTC offered as an example, "instead of cherry pie, try our delicious low fat cherry yogurt - 29 percent fewer calories and 86 percent less fat."[19]

Current FDA regulations do in fact permit certain comparative claims. In addition to the example that FTC provided, the OWG offers the following as examples of comparative claims that are permissible under current regulations:

- One medium apple (80 calories) contains 47% fewer calories than a one ounce serving of potato chips (150 calories).
- Carrots have 93% fewer calories than carrot cake. One 7-inch carrot (78 g) contains 35 calories while one slice of carrot cake with icing (125 g) contains 500 calories.
- Air-popped popcorn (without added toppings) contains one-half the calories of a plain granola bar (98 calories per 3-cup serving of popcorn, 200 calories per 1.5 ounce granola bar).

The OWG recommends that FDA encourage manufacturers to use appropriate comparative labeling statements that make it easier for consumers to make healthy substitutions, including calories. Such comparisons provide valuable information that can be used in making food choices. Moreover, there is a flexible standard for product categories that is intended to facilitate useful comparisons for foods that are generally interchangeable in the diet (for example, "apples have less fat than potato chips") while prohibiting meaningless or misleading claims (58 FR 2302 at 2363, January 6, 1993). Manufacturers have to use judgment in developing claims to ensure that the claims comply with the regulations and are not false or misleading under section 403(a) of the Act.

Disclosure requirements for comparative claims. FTC suggests that FDA "evaluate whether unnecessarily cumbersome disclosure requirements have deterred truthful, non-misleading

comparative label claims for foods." As always, FDA is open to dialogue on such an issue, particularly when a proposal is supported by relevant data and information.

To make a comparative nutrient claim, a food marketer must provide information on the reference food, the percentage by which the nutrient in the reference food has been changed, and the absolute amount of the nutrient in the labeled and reference food (21 CFR 101.13(j)(2)). The agency, however, is not wholly prescriptive as to the actual words used or where all the information is placed on the label.

FTC offered as an example, a baked potato chip that is lower in both calories and fat than a regular potato chip, and indicated that label claims explaining the benefits would be awkward to place (and read) on the front panel. According to FTC, under FDA regulations, the claim would read as follows (italicized phrases may be placed on the back nutrition label):

> "Reduced fat and fewer calories than our Classic Potato Chips. Fat reduced by 85 percent, *from 10 grams per ounce to 1.5 grams per ounce*. Calories reduced by 27 percent, *from 150 calories per ounce to 110 calories per ounce*."

The OWG notes that the FTC example could be more succinct. As FTC suggests, more than 50% of the text may be placed on the back nutrition label. Beyond that, under FDA's current regulations (21 CFR 101.13(j)), the PDP could simply read:

> 85% less fat and 27% fewer calories than our Classic Potato Chips.

B. Restaurants/Industry

Restaurants/Industry Recommendation Highlights:

- ***Short-term***
  - ***Urge restaurant industry to launch a nation-wide, voluntary, and point-of-sale nutrition information campaign for consumers.***
  - ***Encourage consumers routinely to request nutrition information in restaurants***
- ***Long-term***
  - ***Development of a series of options for providing voluntary, standardized, simple, and understandable nutrition information, including calorie information, at the point-of-sale to consumers in restaurants.***
    - ***FDA to seek participating restaurants for a pilot program to study these options in well controlled studies***
    - ***FDA to provide incentives, if necessary, for voluntary industry participation in the pilot program.***
    - ***FDA to evaluate results of the pilot program to***

determine whether further research is warranted before such a program is implemented on a large scale.

- ***Exploration of the concept of third-party certification of weight-loss diet plans and related products.***

- ***Enforcement***
  - ***Together with the FTC, increase enforcement against weight loss products having false or misleading claims.***

The Commissioner directed the OWG to "develop an approach for working with the restaurant industry to create an environment conducive to better informed consumers."

In light of the growing proportion of American meals consumed outside of the home, it is important to enlist the assistance and support of restaurants in addressing population obesity. Since the late 1990s and projecting through 2004, American households are spending approximately 46 percent of their total food budget on food consumed outside the home (ERS, 2003; NRA 2004). During 1994-1996, food consumed outside the home, especially from restaurants and quickservice food establishments, contributed 32 percent of daily intakes of energy calories, 32 percent of added sugars, and 37 percent of fat (ERS, 2000). Thus, food consumed away-from-home is an important part of American diets and more informed dietary choices away-from-home could help reduce calorie over-consumption and the risk of obesity and its associated health problems.

The distribution of meal sources has also shifted over the past few decades, and this shift may be another significant factor in weight gain. Food consumed outside the home has increased from approximately 33 percent of U.S. consumers' food budget in 1970 to approximately 47 percent as of 2002 (ERS, 2003; Young and Nestle, 2002). Over a similar period, total calories from food consumed outside the home, especially from quickservice restaurants, increased from 18 percent to 32 percent. In addition, food consumed outside the home was higher per meal in calories, total fat and saturated fat, as well as was lower in fiber, calcium and iron on a per-calorie basis (Guthrie *et al.*, 2002).

As noted above, under the laws administered by FDA, restaurants are not required to provide nutrition information unless a nutrient content or health claim is made for a food or meal. When claims are made, however, the restaurant need only provide information about the amount of the nutrient that is the subject of the claim. Restaurants may, and many do, provide nutrition information on a voluntary basis. Nevertheless, this nutrition information is often in the form of posters, placemats or menu icons, or on the Internet; rather than at the point-of-sale. Such information is not always readily available or observable at the point-of-sale.

1. FDA Focus Groups on Restaurants

As described in Box 2, FDA recently conducted focus group research in which it asked questions about what type of nutrition information participants would like to see in quickservice restaurants. Participants discussed and reacted to various presentations of nutrition information at restaurants. The questions dealt with four topics: (1) nutrition information; (2) menu board

information; (3) menu board section; and (4) "healthier" symbol. For additional information on FDA's focus groups, see Appendix G.

Nutrition information. Most participants seemed interested in having nutrition information available to them when they eat at fast food and/or quickservice restaurants, though they might not use it every time they eat out. Participants suggested that this information could be presented in many locations in the restaurant including food wrappers, tray liners, brochures, on the take-away bags, posters near the counter, and the menu boards.

Menu board information. Participants reacted to multiple versions of a menu board for a typical fast food restaurant. In general, participants liked having calories listed after meal items and after combo meals. Those who tend to order *a la carte* preferred to have calories listed after each item, while those who usually order a combo meal preferred to have calories listed for the entire meal. Although participants were concerned with multiple macronutrients for foods, having just calories listed was enough for many of them. Participants thought that calories could be a signal for the level of other macronutrients.

Menu board section. Most participants also reacted favorably to the idea of placing healthier options, including meals, in a separate section of the menu board so they could find healthier options at a quick glance.

"Healthier" symbol. Many participants also reacted favorably to a purple keyhole symbol for healthier meals, but some thought that the exact number of calories should be listed as well. Again, the symbol would have to be trusted and consumers would have to understand the meaning of the definition.

2. OWG Restaurant Recommendations

The OWG recommends that FDA encourage restaurants to provide more, and more readily available, nutrient content information at the point-of-sale. The restaurant industry has voiced concern that requiring nutrition labeling for all menu items is infeasible because recipes change frequently, and patrons often request customization of their meals and the number of options available for customization is large. For example, recent National Restaurant Association research indicates that 70% of consumers customize their meals when eating in restaurants.[(20)] Nevertheless, the OWG believes that the restaurant industry could provide some level of nutrition information to its patrons to enhance their ability to make wise food choices. Calculating nutrition information may have been a difficult task for most members of this industry in the past, when such information had to be determined by direct chemical analysis. This task, however, is easier today because nutrient composition databases and software for labeling are readily available. Possibilities for providing nutrition information to consumers include: segregating "healthier" menu items with simple nutrition information in a separate section of the menu; providing icons for individual "healthier" menu items; and presenting nutrition information in locations in the restaurant where patrons can readily use it (i.e., at the point-of-sale).

The OWG also recommends that FDA encourage consumers routinely to request nutrition information in restaurants. Because restaurants respond to consumer demand (as evidenced by comments made by members of the restaurant panel at the November 20, 2003, workshop),

such demand may help create an impetus for more restaurants to provide such information.

The OWG believes that there is a need for research to determine the best way(s) to present nutrient content information to consumers so that they will make healthier choices when eating food away from home. The OWG recognizes, however, that such research will take a substantial period to plan and complete. In the interim, the pervasiveness of the obesity epidemic means that more nutrition information must be presented to consumers in restaurant settings. Accordingly, the OWG has developed both short-term and long-term recommendations

The OWG recommends that in the short-term, FDA urge the restaurant industry to launch a nation-wide, voluntary, and point-of-sale nutrition information campaign for customers.

Over the long-term, the OWG recommends that:

> *(1) Options be developed for providing voluntary standardized, simple, and understandable nutritional information, including calorie information, at the point-of-sale in a restaurant setting.*

Ideally these options should focus on the caloric content and nutritional composition of complete meals rather than individual menu items. Although a focus on total calories is the most useful single piece of information in relation to managing weight, additional information on nutrient content of the meal is also important. This is true, for example, for people with diabetes or coronary heart disease who need to more carefully control their consumption of certain nutrients (e.g., carbohydrates, sodium, fat). An alternative to listing detailed numeric information is to use a graphical representation that conveys the same information using a picture or symbol.

> *(2) FDA seek participating restaurants for a pilot program to study these options in well controlled studies.*

The number of restaurants participating in the pilot program should be large enough to include a variety of locations, cuisines, and average price of menu items. The pilot program needs to be long enough to account for any time required to understand the new menu formats and nutrition information. Participating restaurants would need to provide item-by-item sales data before, during, and after the pilot. Experimental economics methods could substitute partly but not wholly for actual market data to assess the impact of various labeling options on consumer behavior.

FDA could also use this pilot program to explore engaging the restaurant industry as a powerful distribution system for the agency's messages on obesity and its education programs.

> *(3) FDA provide incentives, if necessary, for voluntary industry participation in the pilot program.*

Such incentives could include allowing restaurants to use FDA's name to promote the pilot in advertising, on stickers, and on their menus; and/or coupling the pilot program with an overall FDA education campaign, which may include space on restaurant menus or on separate handouts for FDA messages on healthy lifestyles.

(4) FDA evaluate results of the pilot program.

FDA would need to analyze the results of any pilot program to determine whether further research is warranted before such a program is implemented on a large scale.

In order to pursue these more long-term recommendations, the OWG recommends that FDA work through a facilitator to provide a forum for stakeholders to seek consensus-based solutions to specific aspects of the obesity epidemic in the United States, with a particular focus on food consumed away from home. As a first step, the OWG further recommends that the initiation of such a dialogue be raised at the next meeting of the FDA Science Board.

3. OWG Weight-Loss Diet Plan Recommendations

Just as consumers spend a significant amount of money for foods consumed outside the home, they spend substantial sums on weight-loss diet plans and diet-related products. Such plans and products have the potential to affect all food choices by at least some consumers. The long-term weight or health effects of these and other weight control measures remains unclear (Connors and Melcher, 1993; Ayyad and Andersen, 2000; Saris, 2001; Anderson, *et al.*, 2001; and Phelan, *et al.*, 2003). This raises the question of whether consumers who follow these plans and buy these products understand the health implications, particularly the systematic difficulties of long-term weight management. For these reasons, the OWG also considered the health consequences of using weight-loss diet plans and related products. The OWG concluded that, in the long-term, research needs to be done outside of FDA to determine whether claims for such diet plans and related products have been or can be substantiated. Thus, the OWG recommends that there be an exploration of the concept of third party certification of weight-loss diet plans and related products. The goal is to improve consumer information about the health consequences of their overall dietary choices.

With respect to diet-related products, on December 18, 2002, FDA announced a significant enforcement initiative targeted at misleading claims about dietary supplement-associated health benefits. Dietary supplements are used by an estimated 158 million Americans, and so misleading claims about their health benefits may have significant consequences - not only for wasting consumers' money but also for luring consumers interested in improving their health in wrong directions. Although FDA's enforcement goals related to truthful and non-misleading statements about health benefits apply to all of the products the agency regulates, this initiative was especially focused on products that in recent years have been the subject of important misrepresentation.

As part of the December 18 announcement, FDA released the "Dietary Supplement Enforcement Report" that pledged to closely scrutinize and bring enforcement actions against products identified as "clearly problematic." Dietary supplements that falsely claim effectiveness as treatments for overweight were included among those identified as "clearly problematic."

CFSAN and the Office of Regulatory Affairs have focused their dietary supplement enforcement budgets principally on targeted inspections and, where appropriate, recommending enforcement action against parties who violate the Dietary Supplement Health and Education Act (DSHEA). In terms of the strategies used to enforce DSHEA, FDA has proceeded on

several fronts: (1) traditional enforcement activities (e.g., inspections, warning letters, seizures and injunctions, criminal enforcement); (2) inter-agency and international enforcement; and (3) consumer and industry education.

More recently, in December 2003, FTC staff released a report, *Deception in Weight-loss Advertising Workshop: Seizing Opportunities and Building partnerships to Stop Weight-Loss Fraud* (FTC, 2003). This FTC staff report lays out a number of opportunities for industry and media to assume a leadership role in addressing deceptive weight loss advertising. To complement these efforts, the OWG recommends that FDA continue its enforcement initiative targeted at misleading claims about dietary supplement weight loss products.

C. Therapeutics

Therapeutics Recommendation Highlights:

- ***Convene an FDA advisory committee meeting to address challenges, as well as gaps in knowledge, about existing drug therapies for the treatment of obesity.***
- ***Continue discussions with pharmaceutical and medical device sponsors about development of new obesity therapies.***
- ***Revise 1996 draft guidance on developing obesity drugs and re-issue for comment.***

The Commissioner directed the OWG to "develop an approach for facilitating the development of therapeutics for the treatment of obesity."

The role of obesity in many acute and chronic diseases is well documented. The contribution of obesity to premature mortality through increased risks of diabetes, heart disease, stroke, and cancer, among others, mandates an aggressive, proactive stance by the entire medical community.

1. Background

Modern medicine's experience with weight loss drugs dates to the late nineteenth century when initial enthusiasm for the weight loss properties of thyroid extract were eventually tempered by the negative effects that iatrogenic hyperthyroidism had on lean muscle mass, bone, the central nervous system (CNS), and cardiac function (Schwartz, 1986; Bray, 1976). The next century of obesity drug development saw the introduction of a number of drugs that proved to have significant side effects: Dinitrophenol (cataracts, neuropathy) in 1934; Amphetamine (addiction, CNS and cardiac toxicity) in 1937; Rainbow pills, or digitalis and diuretics (cardiac arrest) in 1967; Aminorex (pulmonary hypertension) in 1971; and Redux (cardiac valvulopathy) in 1996 (Bray and Greenway, 1999).

Prior to 1996, all approved obesity drugs were labeled for short-term treatment of obesity based on pre-approval clinical trials of up to 12 weeks' duration and of limited size by today's standards. Over the past 10-15 years, increasing recognition of several facts have led to changes

in the approach to the treatment of obesity and thus to the study of new drugs for this condition: (1) obesity is a chronic condition with long-term morbid and mortal sequelae; (2) maintenance of weight loss, even while on continued drug therapy (and certainly after discontinuation of drugs) is the rare exception rather than the rule; and (3) maintenance of a "healthy" weight (rather than weight "cycling") is the key to reduced risk for obesity-associated adverse sequelae.

2. FDA's Draft Guidance

In 1996, FDA issued draft guidance entitled "Guidance for the Clinical Evaluation of Weight-Control Drugs." The draft guidance gives recommendations for the design and conduct of phase 1-3 clinical studies aimed at demonstrating the effectiveness and safety of weight-loss medications.[21] This guidance proposed two alternative criteria for effectiveness for drug therapies:

- Mean weight loss in the drug-treated group is 5% greater than the mean weight loss in the placebo group following one year of treatment.
- The proportion of patients that lose at least 5% of their baseline weight is greater in the drug vs. the placebo group.

3. Existing Therapies

Under the criteria in the 1996 draft guidance, three drugs have been approved for the long-term treatment of obesity: dexfenfluramine (Redux) in 1996 (withdrawn in 1997 for safety reasons), sibutramine (Meridia) in 1997, and orlistat (Xenical) in 1999. In addition, a number of drugs were approved prior to 1996 for the short-term (e.g., a few weeks) treatment of obesity (e.g., phentermine (Adipex) and diethylpropion (Tenuate)).

FDA-approved drugs for the long and short-term treatment of obesity are indicated for use by those patients with: (1) a body mass index of > 27 kg/m^2 when accompanied by obesity-related comorbidities such as hypertension, diabetes, and dyslipidmeia; or (2) a body mass index > 30 kg/m^2.

For patients with extreme obesity (those with BMIs at or over 40), for whom no other measures have been effective in promoting weight loss, surgical or device-mediated gastroplasty is increasingly employed. Worldwide, over 100,000 of these devices have been implanted over the past 8 years. In the United States alone, tens of thousands of devices are implanted each year to restrict the size of the stomach and thus severely limit food intake. Despite serious complications, gastroplasty procedures as well as device implantations are effective for some individuals, with average durable loss of 35-40% of excess (over ideal) weight.

4. OWG Therapeutics Recommendations

Ideally, individual consumers will avoid becoming overweight or obese through diet and exercise. Yet the OWG recognizes that obese and extremely obese individuals are likely to need medical intervention to reduce weight and mitigate associated diseases and other adverse health effects. The OWG concurs with agency plans to (1) convene an FDA advisory committee meeting to address challenges, as well as gaps in knowledge, about existing therapies (i.e., head-to-head comparisons of marketed drugs, cardiovascular endpoint studies); (2) continue

discussion with pharmaceutical and medical device sponsors about new obesity medical products; and (3) revise 1996 draft guidance on developing obesity drugs and re-issue for comment.

D. Research

Research Recommendation Highlights:

- ***Pursue research on obesity prevention with USDA/ARS.***
- ***Support and collaborate, as appropriate, on obesity-related research with others, including NIH***
- ***Pursue obesity related research in the following five areas:***
  - ***Information used to facilitate consumers' weight management decisions.***
  - ***Relationship between overweight/obesity and food patterns.***
  - ***Incentives to product reformulation***
  - ***Potential for FDA regulated products unintentionally to contribute to or result in obesity***
  - ***Translational research conducted by the National Center for Toxicological Research (NCTR) and CFSAN's Office of Applied Research and Safety Assessment (OARSA)***

The Commissioner directed the OWG to "identify applied and basic research needs relative to obesity that include the development of healthier foods as well as a better understanding of consumer behavior and motivation."

1. Joint Research with USDA/ARS

As part of its research efforts, the OWG recommends that FDA collaborate with USDA/ARS on a national obesity prevention conference to be held in October 2004. The conference will draw on the expertise of both the public and private sector scientific communities to provide guidance for research agendas in the short- and long-term to address obesity prevention from a variety of scientific and other disciplines. Such disciplines will include diet and nutrition, behavioral and economic science, and research involving exercise, education, integrated programs, and outreach.

2. Survey of Research

The OWG focused on three areas of research related to its charge: (1) "labeling information"[22] and consumer perceptions and dietary behaviors with regard to weight management; and (2) support for safety evaluation with respect to the potential for FDA regulated products unintentionally to contribute to or result in obesity; and (3) translational research conducted by FDA's National Center for Toxicological Research and CFSAN's Office of Applied Research

and Safety Assessment. to enable the agency to use the basic scientific research conducted by such agencies as the NIH in FDA's regulatory activities. Of these three, the OWG considers the first two to be more directly and immediately relevant to its charge. Translational research, because of its link to basic nature, takes a long time to yield practical results. Nevertheless, the OWG believes FDA should continue to conduct translational research in order to gain a better understanding of obesity.

Based on a review of the relevant research as well as comments provided during a variety of public meetings, the OWG has identified several knowledge gaps related to the two research areas above. The OWG recommends that further obesity-related research be conducted in the following areas: (1) information used to facilitate consumers' weight management decisions, (2) the relationship between overweight/obesity and food consumption patterns, (3) incentives to product reformulation, and (4) the potential for FDA-regulated products unintentionally to contribute to or result in obesity, and (5) the extension of basic research findings to the regulatory environment through translational research. In addition, the OWG recommends that FDA pursue collaborations with other groups who are undertaking obesity research such as NIH, which has recently issued an obesity research agenda, and CDC.

Information used to facilitate consumers' weight management decisions. The OWG recommends conducting additional qualitative and quantitative research with an emphasis on (1) consumer reaction to and effectiveness of current packaged food labeling and possible changes to the food label (e.g., highlighting calories, listing the quantitative amounts for all nutrients in multi-size packages, and using "healthy" symbols, graphic devices, or caloric/nutrient density indicators), (2) consumer reaction to and effectiveness of current restaurant nutrition information and possible changes (e.g., listing nutritional information such as calories, fat and sodium for both *a la carte* items and meals and using "healthy" symbols), and (3) consumer dietary behavior and attitudes toward weight management.

Relationship between obesity and food consumption patterns. The OWG recommends conducting research to evaluate the relationship between obesity in adults and children and the frequency of foods obtained from and/or consumed in different locations (e.g., home cooked meals, packaged foods, and quickservice establishments/restaurants) and with respect to socioeconomic status and vulnerable populations (e.g., Hispanic Americans, African Americans, American Indians, and the elderly). This research would be conducted in collaboration with the Economic Research Service of the USDA using CDC and National Health and Nutrition Education Survey data to evaluate these relationships.

Incentives to product reformulation. The OWG recommends conducting further research with the packaged food and restaurant industries in addition to that currently being conducted by OASPE in collaboration with FDA (FDA, 2003). This research would (1) examine whether the incentives (e.g., label prominence and other label characteristics of calorie and weight management information) and barriers (e.g., food additive and claims approval processes and the regulatory policy related to standards of identity and fortification) to reformulation identified by the packaged food industry during previous discussions are real or perceived, and (2) expand the scope of the research conducted by OASPE to include additional discussions with key restaurant industry, including quickservice, personnel regarding the barriers and incentives to the development/reformulation of healthier restaurant foods.

Potential for FDA-regulated products to unintentionally contribute to or result in obesity.

Although most FDA-regulated products are intended to be used or consumed for purposes other than weight management, weight gain may be an unintentional adverse side effect associated with use of some of these products. In general, for both foods and drugs, weight gain or obesity has not consistently been measured, evaluated, or considered as an adverse effect when designing study protocols or evaluating submitted research results. Strategies to systematically evaluate this endpoint are needed as part of the safety assessment for FDA-regulated foods and drugs. Thus, the OWG recommends conducting research to investigate (1) the promotion of weight gain as an adverse side effect of FDA-regulated drugs and whether this is a factor that should be taken into account regarding drug safety and (2) the development of animal model assessment strategies that encompass the evaluation of long-term effects on weight gain as a safety assessment parameter.

Translational research. Translational research is essential for FDA to use basic research from other agencies and academic institutions in developing regulatory policies and actions. Thus, the OWG recommends extending basic research on (1) developmental imprinting[23] to differentiate among food components and eating behaviors of neonates, or nutrient/food component exposures of fetuses via maternal diets, with regard to weight management challenges in adolescence and adulthood, (2) biomarker and effects-evaluation techniques through emerging genomics, proteomics and metabolomics technologies to identify how FDA-regulated products modify risk factors and susceptibilities for weight gain, obesity, and co-morbidities, and (3) development of animal models to evaluate the effects of diets and dietary components, drug therapies, and medical device uses on long-term weight maintenance, health and longevity. The OWG further recommends that FDA take into account translational as well as other obesity-related research being done by NIH, as it considers future research in these areas.

VI. Stakeholder Investment to Help Ensure Results

Stakeholder Investment Recommendation Highlight:

- ***Continue to promote and engage in active dialogue with invested stakeholders.***

The Commissioner charged the OWG to set out specific means for developing and implementing "an active dialogue with outside invested stakeholders including consumers groups, academia, and the food and restaurant industry on developing a framework for consumers to receive messages about reducing obesity and achieving better nutrition."

A. Background

Recognizing the high level of interest in obesity among FDA's many stakeholders, the OWG initiated a process for establishing ongoing relationships with individuals and organizations from all sectors. A key aspect of this process included providing the public with multiple opportunities to become involved in a dialogue with the OWG on its activities and the issues associated with helping consumers address the problem of obesity.

As one of its first major outreach initiatives, the OWG sponsored a public meeting on October 23, 2003,[24] to accomplish several objectives:

- To initiate a discussion of FDA's role and responsibilities in addressing the major public health problem of obesity;
- To focus on issues related to promoting better consumer dietary and lifestyle choices that have the potential to significantly improve the health and well-being of Americans; and
- To obtain stakeholder views on how best to build a framework for messages to consumers about reducing obesity and achieving better nutrition.

Approximately 320 attendees representing diverse stakeholder viewpoints registered to participate in this discussion, with nineteen organizations making formal presentations on issues associated with the six focus questions. These nineteen organizations represented science/research, academia, consumers, health and medical associations, industry, and advocacy groups. In addition to the formal presentations given at the October 23 public meeting, interested and concerned stakeholders submitted written comments to Docket No. 2003N-0338 on various aspects of the six focus questions.

The scope of the discussion at this meeting, and at two subsequent roundtable meetings (held with health professionals/academicians and with consumer groups, on December 15-16, 2003, respectively) centered on the following six focus questions:

1. What is the available evidence on the effectiveness of various education campaigns to reduce obesity?

Stakeholders regarded education as an essential component of FDA's contribution to public health efforts to confront the problem of obesity. Stakeholders consistently reinforced FDA's leadership role in educating the public about the food label, good nutrition, and healthy diets.

Stakeholder comments focused on four key areas: (a) effectiveness of existing education campaigns; (b) type of education campaigns needed; (c) what campaigns should address; and (d) what messages are likely to affect weight gain, weight management, or weight loss.

2. What are the top priorities for nutrition research to reduce obesity in children?

Stakeholders were particularly concerned about childhood obesity. Stakeholders emphasized the importance of parental involvement in efforts to address childhood obesity. The views focused on the scope of the problem, as well as on the research on activities that are needed to address the issue of childhood obesity.

3. What is the available evidence that FDA can look to in order to guide rational, effective public efforts to prevent and treat obesity by behavioral or medical interventions, or combinations or both?

Stakeholders expressed a range of views and perspectives about what would inform FDA decisions in preventing and treating obesity.

4. Are there changes needed to food labeling that could result in the development

of healthier, lower calorie foods by industry and the selection of healthier, lower calorie foods by consumers?

Stakeholders were highly interested in participating in the area of food labeling. The views focused on (a) general advice; (b) calories; (c) energy balance; (d) serving sizes; (e) current health-related information on the label; (f) consumer education on the food label; (g) messages on the food label; and (h) expanding nutrition information availability in restaurants.

5. What opportunities exist for the development of healthier foods/diets and what research might best support the development of healthier foods?

Stakeholders provided a diverse array of research needs, creative incentives for the development of healthier foods/diets, and general advice.

6. Based on the scientific evidence available today, what are the most important things that FDA could do that would make a significant difference in efforts to address the problem of overweight and obesity?

Stakeholder views related to three major categories: (a) food labels; (b) research; and (c) education.

On November 20, 2003, FDA, in conjunction with OASPE, sponsored a workshop on "Exploring the Connections Between Weight Management and Food Labels and Packaging."[25] The two major issues explored at this workshop were:

- Current food labels and packaging: Effects on weight management and reduced risk of overweight and obesity and
- Data supporting options for change

This daylong workshop involved presentations by researchers, academicians, and public health officials, who discussed issues such as the effect of portion/package size, shape and structure on consumption (e.g., comments by Brian Wansink in transcript of November 20 workshop); and presentations by representatives of the restaurant industry, who addressed issues surrounding provision of nutrition information in restaurants.

The OWG organized the comments to Docket No. 2003N-0338 into a searchable database that informed preparation of this report.

FDA also met with representatives of the packaged food and restaurant industries to learn about their obesity-related activities.

B. OWG Stakeholder Investment Recommendations

The OWG believes it is worthwhile to maintain contacts with stakeholders concerned about the obesity issue both to benefit from their continued involvement and to ensure that, to the extent possible, collective obesity efforts are mutually supportive.

VII. Overall Conclusions

In response to the charge to the OWG, this report provides a range of recommendations for addressing the obesity epidemic. These recommendations address multiple facets of the obesity problem under FDA's purview, including developing appropriate and effective consumer messages to aid consumers in making wiser dietary choices; formulating educational strategies in the form of partnerships, to support the dissemination and understanding of these messages; specific new initiatives to improve the labeling of packaged foods with respect to caloric and other nutritional information; initiatives enlisting and involving restaurants in the effort to combat obesity; the development of new therapeutics; the design and conduct of effective research in the fight against obesity; and the continuing involvement of stakeholders in the process.

As noted previously in this report, achieving ultimate success against obesity will occur only as a result of the complementary efforts over time by many concerned sectors of our society. It is the belief and the hope of the OWG that the recommendations contained in this report, when carried out by FDA in concert with the complementary ongoing and planned efforts of other sister DHHS agencies and other agencies of government, will make a significant impact in reversing current trends.

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Notes:

(2) National Institutes of Health (NIH) clinical guidelines (http://www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/risk.htm#limitations) define "overweight" in adults as a body mass index (BMI) of 25.0 to 29.9, and "obesity" as a BMI of 30.0 or higher. BMI (see Text Box at Appendix B) is defined as the ratio of a person's bodyweight in kilograms divided by the square of his or her height in meters.

(3) For additional information on factors contributing to obesity see CDC webpage (http://www.cdc.gov/nccdphp/dnpa/obesity/contributing_factors.htm)

(4) In children, the BMI is expressed as percentile growth that is based on gender-and age specific growth charts.

(5) When the OWG was formed, Joseph A. Levitt was the Director of CFSAN, and the OWG vice-chair. As of January 5, 2004, Dr. Brackett became director of CFSAN, and assumed the role of vice-chair.

(6) For a further discussion of energy balance see, *Dietary Reference Intakes* - Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids Part 2, Chapter 12 Physical Activity; 12:1-39 (Institute of Medicine of the National Academies, 2002) and references cited therein.

(7) Although alcoholic beverages are not a focus of this report, there is some interest in having calorie and other nutrition information declared on the label of such beverages, as evidenced by a recent petition from the Center for Science in the Public Interest (CSPI) submitted to the Tax and Trade Bureau of the Treasury Department. In a letter dated December 17, 2003, to DHHS Secretary Thompson, CSPI requested that DHHS support the petition.

(8) As noted earlier in Section II.A.1., there is much discussion in the field of nutrition concerning the specific macronutrient source of calories, but given the charge to focus on obesity, the OWG believes that a primary focus on calories is appropriate.

(9) For more information on *Steps to a HealthierUS* see http://www.healthierus.gov/steps/index.html

(10) For more information on the *HealthierUS* Initiative see http://www.healthierus.gov/

(11) In addition, the focus groups explored what type of nutrition information they would like to see in quickservice restaurants (see section V.B.1.of this report). Participants discussed and

reacted to various presentations of nutrition information at restaurants.

(12) IFIC states that its mission is to communicate science-based information on food safety and nutrition to health and nutrition professionals, educators, journalists, government officials and others providing information to consumers. IFIC states that its purpose is to bridge the gap between science and communications by collecting and disseminating scientific information on food safety, nutrition and health and by working with an extensive roster of scientific experts and through partnerships to help translate research into understandable and useful information for opinion leaders and ultimately, consumers. IFIC is supported primarily by the food, beverage and agricultural industries.

(13) The %DV indicates the amount of a nutrient present in a serving in relation to reference levels for a daily diet. The reference levels for vitamins and minerals are based on Recommended Dietary Allowances established by the National Academies; the reference levels for macronutrients are based on recommendations in the *Dietary Guidelines for Americans* or as established by public health organizations. For macronutrients whose recommended intake levels are based on caloric intake (e.g., saturated fat intake should be less than 10% of calories), the %DV is calculated for a 2,000 calorie diet.

(14) USDA's Healthy Eating Index is a summary measure of overall diet quality. It provides a picture of the type and quantity of foods people eat and the degree to which diets comply with specific recommendations in the *Dietary Guidelines for Americans* and USDA's Food Guide Pyramid. For further information go to http://www.usda.gov/cnpp/healthyeating.html

(15) The Food Labeling Compliance Program gives instructions to FDA Field Offices that describes food labeling enforcement strategies and identifies/highlights specific areas where resources should be targeted with regard to the accuracy of the food label.(currently on the Internet at: http://www.cfsan.fda.gov/~comm/cp21008.html)

(16) For a further discussion on carbohydrates, see *Dietary Reference Intakes* - Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids Part 1, Chapter 6 Dietary Carbohydrates: Sugars and Starches 6:1-57 (Institute of Medicine of the National Academies, 2002) and references cited therein.

(17) Guidelines for Use of Nutrition Claims (CAC/GL 23-1997).

(18) Guide to Food Labeling and Advertising. Section VI. Nutrient Content Claims 6.1.9(c).

(19) This example also contains an express nutrient content claim ("try our delicious low fat yogurt"), and two relative claims ("29 percent fewer calories" and "86 percent less fat"). Hence, the statement, as written, would need to meet the regulatory requirements for these types of claims, and would also need to provide serving size information that would allow for appropriate comparison between the cherry pie and the cherry yogurt.

(20) From remarks by Hudson Riehle of the National Restaurant Association at the November 20, 2003, workshop "Exploring the Connections Between Weight Management and Food

Labels and Packaging" (http://www.fda.gov/ohrms/dockets/dockets/03n0338/03n0338-tr.htm)

(21) On January 26, 2004 (69 FR 3588), FDA issued a *Federal Register* notice specifically to solicit comments on this previously published draft guidance. FDA is interested in incorporating the latest scientific advances in the field of obesity and drug development into an amended obesity guidance document. Once the agency revises the draft, FDA will issue the guidance again for comment before finalizing the guidance.

(22) For the purposes of V.D.2., "labeling information" includes possible changes to the NFP, possible changes to the PDP, graphic devices, caloric/nutrient density indicators, and nutrient content claims.

(23) The developmental imprinting hypothesis suggests that the increase in childhood obesity is, in part, a result of an epigenetic effect of poor nutrition or exposure to some toxic agent during the perinatal period when metabolic pathways are being established in the fetus and neonate, creating a dysfunctional metabolic pathway. As the child ages, these dysfunctional metabolic pathways, in conjunction with other factors, such as inadequate exercise, may become sufficient to cause or contribute to overweight or obesity. This developmental programming hypothesis, developed from epidemiological data, has also been recently extended to animal models.

(24) In the *Federal Register* of October 8, 2003 (68 FR 58117), FDA announced this public meeting. Transcript of the meeting is available in FDA Docket No. 2003N-0338, and as of the date of this report, available on the Internet at (http://www.fda.gov/ohrms/dockets/dockets/03n0338/03n0338-tr.htm).

(25) In the *Federal Register* of October 17, 2003 (68 FR 59795), FDA announced this public workshop. On November 19, 2003 (68 FR 65303), FDA amended its original announcement to reflect that the agency was requesting comments regarding the workshop. Transcript of the workshop is available in FDA Docket No. 2003N-0338, and as of the date of this report, available on the Internet at (http://www.fda.gov/ohrms/dockets/dockets/03n0338/03n0338-tr.htm)

(26) This listing includes references in the Report and Appendices B and H

Office of Nutrition, Labeling, and Dietary Supplements
April 2008

Guidance for Industry

A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods

Additional copies are available from:
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http://www.cfsan.fda.gov/guidance.html

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
April 2008

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Guidance for Industry[1]

A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. INTRODUCTION

"A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods" is intended to be guidance to facilitate compliance with the new regulations. It does not bind the agency, nor does it create or confer any rights, privileges, or benefits for or on any person. While "A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods" represents the best advice of FDA, it does not have the force and effect of law. The interpretations presented herein are obviously subject to the requirements of law both in the statute and in the regulations.

The FDA will continue to update and issue additional editions of guidance as resources permit. Questions will be collected by FDA from correspondence and other inquiries that it receives. FDA will also consider specific submissions of questions for inclusion in future editions of this

guidance. Questions concerning the interpretation of the requirements of the food labeling regulations should be submitted to the Office of Nutrition, Labeling, and Dietary Supplements (HFS-800), Food and Drug Administration, 5100 Paint Branch Ave., College Park, MD 20740.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The Nutrition Labeling and Education Act of 1990 (the NLEA) and the final regulations to implement the NLEA (January 6, 1993), provide for a number of fundamental changes in how food is labeled, including requiring that nutrition labeling be placed on most foods, requiring that terms that characterize the level of nutrients in a food be used in accordance with definitions established by FDA, and providing for the use of claims about the relationship between nutrients and diseases or health-related conditions. These changes apply to virtually all foods in the food supply, including, in large measure, to foods sold in restaurants.

Following publication of the January 6, 1993, final rules, FDA issued technical amendments that correct unintended technical effects contained in several of the various rules in the Federal Register of August 18, 1993 (58 FR 44020). Nonetheless, a large number of questions were raised by industry, consumers, and others concerning the interpretation of these various final rules. Consequently, the former Office of Food Labeling (OFL)/Center for Food Safety and Applied Nutrition (CFSAN)/FDA developed the "Food Labeling, Questions and Answers" (August 1993, Updated June 2007) as an efficient way to provide answers to some of the more common questions that had been raised concerning the food labeling regulations. The agency also issued "Food Labeling: Questions and Answers, Volume II; A Guide for Restaurants and Other Retail Establishments" as part of a continuing effort to respond to concerns. This Guide is updated in this document, and responds to questions raised since publication of the first guide, including questions related to the labeling of foods sold in restaurants.

III. NUTRITION LABELING OF RESTAURANT FOODS (21 CFR 101.10)

1. **I understand that foods served or sold in restaurants are exempt from nutrition labeling if they do not bear a claim. Once they bear a claim, the restaurant must provide nutrition information upon request for the food that bears the claim. Does a restaurant have to use the Nutrition Facts format to provide nutrition information?**

   Answer: No. FDA is not requiring full nutrition labeling for restaurant foods, nor is it requiring that nutrition information be presented in the Nutrition Facts format. Because restaurant foods tend to be prepared or sold differently from foods from other sources, FDA has amended 21 CFR 101.10 to provide a number of flexibilities for restaurants in how they determine the nutrient content of a food

(e.g., using data base analysis or other reliable sources of nutrient information) and in how this information may be presented to consumers (e.g., in various formats and by reasonable means, such as in a flier or notebook) January 6, 1993, 58 FR 2302 at 2410 (available in PDF, 22.87 MB).

2. **Which foods can take advantage of the flexible provisions of 21 CFR 101.10 (Nutrition labeling of restaurant foods)?**

   Answer: Section 101.10 was established to provide flexibility to restaurants and similar establishments when it is the restaurateur who is responsible for determining nutrient content or providing nutrition labeling for foods that are served or sold in such establishments. The nutrition labeling provisions in 21 CFR 101.10, and discussed herein, also extend to the restaurant-type foods described in 21 CFR 101.9(j)(3) provided they meet the requirements of that section (i.e., they are: similar to foods served in restaurants, ready-to-eat, not for immediate consumption, and prepared or processed primarily at the retail location from which they are sold).

3. **Can a commercial food manufacturer use the nutrition labeling provisions of 21 CFR 101.10 (Nutrition labeling of restaurant foods) for foods that he/she manufactures, packages, and labels for sale or use in restaurants? Would it matter if the food was sold only in restaurants?**

   Answer: No. 21 CFR 101.10 was established to provide flexibility to restaurants and similar establishments when it is the restaurateur, not a manufacturer, who is responsible for determining nutrient content or providing nutrition labeling for food sold in such establishments. Consistent with the agency's treatment of commercially packaged fresh fish and nuts (See Food Labeling Guidance), when a manufacturer or packer labels a packaged food, including foods sold only in restaurants, the nutrition information must be presented according to the requirements in 21 CFR 101.9 (Nutrition Facts) and would be judged by the compliance criteria of that section.

   The exception would be foods sold for use in restaurants but not served to consumers in the package in which they are received (e.g., large, institutional size containers) (21 CFR 101.9). Because such foods are exempt from nutrition labeling requirements, even if they bear a claim, voluntary nutrition labeling may be presented for these foods by any reasonable means, including those provided for in 21 CFR 101.10.

4. **Does nutrition information have to appear on the same labeling that bears a nutrient content claim or health claim? For example, would a claim for a food listed on a placard require nutrition information on the placard also?**

   Answer: No. Section 101.10 requires that nutrition information be available upon request. It may appear on the same or different labeling from that which bears the claim. It may be presented in various forms, including those specified in 21 CFR 101.45 (e.g., displayed at point of purchase by an appropriate means, such as

affixing it to the food, by posting a sign, or by making the information readily available in a brochure, notebook, or leaflet, in close proximity to the foods), Nutrition Facts (21 CFR 101.9), and by other reasonable means (21 CFR 101.10).

5. **A restaurant prepares and sells a number of foods that bear a claim, including an ice cream sandwich made with "low fat ice cream." The ice cream sandwich may be served for immediate consumption or it may be wrapped and sold from a self-service cold case in the restaurant. The wrapped sandwiches sold from a self-service case bear a claim on the package label. The restaurant provides consumers, upon request, with a brochure containing nutrient content information, according to 21 CFR 101.10, for the foods it serves for immediate consumption that bear claims. Can the restaurant use the same brochure to meet nutrition labeling for the wrapped ice cream sandwich that bears a claim on its label or does it have to put Nutrition Facts on each package?**

   Answer: Foods that are served or sold in restaurants and similar establishments may bear nutrition information according to 21 CFR 101.10, even if the food is sold in packaged form and a claim or other nutrition information appears on the package label provided the food is labeled by the restaurateur.

6. **How may nutrition information be presented for restaurant-type foods that are primarily processed or prepared at the retail location from which they are sold when that location does not have facilities for immediate consumption? Please address salads prepared and sold in-house in your answer.**

   Answer: Many restaurant-type foods (i.e., ready-to-eat but not for immediate consumption) that are prepared at the same retail location from which they are sold have similar needs for flexible nutrition labeling as foods served or sold by restaurants (e.g., the foods are generally hand assembled and, therefore, subject to individual product variations). Thus, the general provisions of 21 CFR 101.10 discussed in this section are available to restaurant-type foods that meet the criteria set out in 21 CFR 101.9(j)(3). For example, if a grocer prepares and sells a "low fat" potato salad in-house, nutrition labeling must, at a minimum, provide information on the fat content of the food. This information would be available to the grocer from his/her reasonable basis determination that the food meets FDA's definition for the claim. Nutrition information for a restaurant-type food that bears a claim must be available to consumers upon request and may be presented by reasonable means (e.g., in a brochure or posted at point of purchase).

7. **Can a restaurant provide nutrition information to consumers orally, or must it be presented in written form?**

   Answer: Nutrition information for restaurant and restaurant-type foods may be provided by any reasonable means, including orally. A statement from a waiter, for example, that a "low fat" meal contains less than 10 grams of fat will serve as the functional equivalent of full nutrition labeling. In such a case, however, the restaurant should also have nutrition information in writing, as a back-up, to ensure that the information communicated by the staff is valid.

8. **I understand that nutrition information for packaged foods must be provided for the food "as packaged." Information for the nutrient values of the food "as prepared" is voluntary and would be listed in a second column. What is the basis for nutrition labeling of a food served in a restaurant (not in packaged form), the uncooked ingredients or the prepared food?**

   Answer: Nutrition information must be provided on the basis of the food as packaged or purchased by the consumer (21 CFR 101.9(b)(9)). Thus, nutrition labeling of a ready-to-eat food served in a restaurant or similar establishment would be based on the nutrient content of a single serving of the finished product as it is marketed for purchase by consumers.

9. **Which nutrients should a restaurant include in nutrition labeling?**

   Answer: At a minimum, restaurants must provide information on the nutrient that is the basis for the claim (e.g., "low fat, this meal contains 10 grams of fat").

10. **How does a restaurant determine which nutrients are the basis for a claim (i.e., which nutrients must be included in nutrition labeling)?**

    Answer: Nutrients that are the basis for a claim include all nutrients that are relevant in determining whether a food meets the definition for a claim. For example, fat claims are based on the fat content of a food. Thus, nutrition information for a "low fat" food must include information on the level of fat in the food bearing the claim. Cholesterol claims are based on the cholesterol content of the food and are allowed only when a food contains 2 grams or less saturated fat per RACC (2 grams or less saturated fat per 100 grams of food for meals and main dish products). Thus, nutrition information for a food bearing a cholesterol claim must include information on both the cholesterol and the saturated fat content of the food. Health claims include both the general health claims requirements (i.e., that disqualifying levels not be exceeded) and the nutrient requirements for the specific claim (see question 43). This information (e.g., information about the level of the nutrients that are the basis for the claim) should be readily available to a restaurant from its determination that the food conforms to the definition of a claim. (Definitions for nutrient content claims and requirements for health claims are summarized in Appendices B, C, and D of the Food Labeling Guide.)

11. **If a restaurant wants to provide information on additional nutrients (e.g., nutrients that are not the basis for a claim) can it do so?**

    Answer: Yes. While the provision of information on nutrients that are the basis for a claim is the minimum requirement for nutrition labeling of restaurant foods, FDA encourages restaurants to provide consumers with as much information on the nutrient content of the food as possible.

12. **If a restaurateur chooses to voluntarily provide nutrition labeling for a food that is otherwise exempt, how may this be accomplished?**

Answer: Generally, the restaurateur may provide voluntary nutrition information according to the options available to foods that bear a claim (i.e., 21 CFR 101.9 (Nutrition Facts), 21 CFR 101.45 (voluntary program for raw fruits, vegetables, and fish), or 21 CFR 101.10 (reasonable means)). For example, a restaurateur may choose to provide nutrient content information in a statement such as "Garden salad with grilled chicken, contains 390 calories, 8 g fat, and 13 mg cholesterol." Because nutrition labeling requirements are triggered by a nutrient content claim, health claim, or other nutrient content information, the food would no longer be exempt from nutrition labeling. However, this information can itself serve as the functional equivalent of nutrition labeling, and no additional labeling would be required.

13. **Would FDA consider a telephone number to be a reasonable means of providing nutrition information for a food sold in a restaurant or other vending facility and which makes a claim?**

Answer: No. Once a food bears a claim, nutrition information must be readily accessible to consumers (e.g., on the label attached to the food or in labeling at point of purchase). Vending machine foods that are sold in packaged form should have required labeling on the product visible to the consumer prior to purchase or be otherwise displayed at point of purchase. With respect to foods prepared or processed by the vending machine (e.g., soup dispensed into a cup), the mandatory information may be displayed on the vending machines.

14. **Must a restaurant include % Daily Values in its nutrition labeling?**

Answer: Not necessarily. Nutrition information may be presented in a variety of formats. However, the agency considers % Daily Values to be very important information and encourages such a declaration whenever practicable. If a restaurant chooses to use the Nutrition Facts format, labeling must contain all information, including % Daily Values, required for the chosen format.

15. **Can a restaurant present nutrition information in a modified version of the Nutrition Facts format? For example, can nutrition information be presented in a format that resembles the Nutrition Facts but that contains elements that were modified or eliminated compared to the requirements of 21 CFR 101.9?**

Answer: No. As stated in response to question 1, a restaurant may choose to present nutrition information in a variety of formats. FDA would not object to a restaurant food bearing nutrition information according to the different Nutrition Facts formats set out in 21 CFR 101.9 (e.g., the simplified format, the shortened format, an aggregate display, or a linear display) so long as labeling contains all required elements of the chosen format and it meets the requirements of 21 CFR 101.10 (i.e., it includes information on the nutrient that is the basis for the claim).

16. **FDA's requirements for the Nutrition Facts format are fairly specific with respect to type style, type size, and placement. Does the agency have similar requirements for nutrition labeling of restaurant foods?**

Answer: It depends on the format used. Nutrition labeling for restaurant foods may be presented in various formats, including Nutrition Facts (21 CFR 101.9), following the format established for raw fruit, vegetables, and fish (21 CFR 101.45), and by other reasonable means (e.g., a statement such as "low fat, this food contains no more than 3 grams of fat" in a brochure or notebook) (21 CFR 101.10).

Consistent with its flexible approach towards restaurant food labeling, FDA has not established standardized type size or placement requirements in 21 CFR 101.10. Labeling that is easily accessible to consumers, that contains all required nutrition information, and that is presented clearly and legibly, would be generally consistent with the "reasonable means" provision of 21 CFR 101.10.

17. **Data base analysis indicates that a food contains 277 calories, 464 mg sodium, 39.22 g protein, and 5.81 g fat per serving. Can a restaurant use the same numbers that are generated by data base analysis (or provided in a cookbook or other source of nutrient content information) directly in its nutrition labeling?**

    Answer: Yes. However, labeling that declares nutrient values in a way that implies an unwarranted degree of accuracy could be misleading. To avoid the impression of unwarranted accuracy, as well as to make nutrition labeling easier for consumers to review and understand, restaurants are strongly encouraged to follow the rounding rules set out in 21 CFR 101.9 (see Appendix H of the Food Labeling Guide). To be consistent with these rules, the above values should be declared as 280 calories, 460 mg sodium, 39 g protein, and 6 g fat.

18. **If an airline provides passengers with a special meal upon request (e.g., a "low sodium" meal), would this be a claim subject to the NLEA? How can nutrition labeling be accomplished?**

    Answer: If, in response to a special request, the airline provides a special meal and represents that the food or meal is, for example, "low sodium," "reduced sodium," or "low in fat," the airline is making a nutrient content claim for the food, and the food must meet the definition for the claim. Nutrition information must be provided for the nutrient amounts that are the basis for the claim (e.g., "low fat, this meal contains 10 grams of fat") and may be provided by reasonable means (e.g., on the back of a card wrapped with the meal identifying the meal as a special request or in a binder available from the flight attendants).

19. **Is a restaurant required to provide information on the amounts of nutrients that are not the basis for a claim? For example, if a food bears a "low fat" claim but the sodium content of the food exceeds a certain level, does the restaurant need to include sodium in its nutrition labeling?**

    Answer: FDA encourages restaurants to provide as much nutrition information as possible to consumers. However, the NLEA exempts restaurant foods from the referral and disclosure statements that must appear on the principal display panel of a packaged food if the food bears a claim and it contains a nutrient (i.e., fat,

saturated fat, cholesterol, or sodium) at a level greater than the disclosure levels set out in 21 CFR 101.13(h). Further, FDA's regulations provide that, in a restaurant situation, information on the nutrients that are the basis for the claim may serve as the functional equivalent of full nutrition labeling. Thus, in the above example, information about the fat content of the food bearing a "low fat" claim would serve as the functional equivalent of full nutrition labeling.

20. Can a restaurant present nutrition information for an item based on an optional form of serving or preparation? For example, if it serves a grilled chicken breast with the skin attached, can it provide nutrient content information on the basis of the chicken with the skin removed?

Answer: As stated in response to question 8, nutrition information must be presented for a food based on the form in which the food is served or sold to consumers. The restaurant may, however, voluntarily provide a second set of information based on an optional method of preparation or serving, e.g., the chicken breast with skin removed.

If a claim is made for a food, and the food or meal only meets the definition of the claim based on an optional method of preparation (e.g., if the food may be prepared, on request, with half the oil normally used), this fact must be clearly communicated to consumers.

21. I understand that nutrient content information should be based on the labeled serving size for a food. In a restaurant situation, labeled serving size would be the same as an actual or portioned serving (e.g., the amount of food provided by the restaurant in a single serving). What basis should a restaurant use for nutrition labeling if it has no control over serving size? For example, how should a restaurant declare the nutrient content of items offered in a self-service soup and salad bar?

Answer: Even if it is not the restaurant that portions a food, the restaurant may still have a logical frame of reference for serving size. For example, if a restaurant provides patrons with containers or serving utensils that have a given capacity (e.g., soup bowls, salad dressing ladles) and if it is reasonable to expect that consumers may fill the containers to capacity, the restaurant should base nutrient content information on of the amount of food the container could hold. However, if a food bears a claim, it must meet the definition for the claim based on its RACC, regardless of labeled serving size (see question 79).

Nutrient content information for discrete items available at a self-service salad bar (e.g., muffins, whole fruit, or slices of bread) should be declared on the basis of the number of unit items that is closest to the RACC for the food (21 CFR 101.19 (b)(2)(ii)).

22. FDA has stated that a restaurant may present nutrition information in a statement such as "contains X amount of a nutrient." Does labeling also need to specify serving size (e.g., does it need to list the weight of the food or meal)?

Answer: It depends. FDA encourages restaurants to provide as much nutrition related information as possible, including information on serving size. However, consistent with the agency's flexible approach to nutrition labeling on restaurant foods, FDA will accept labeling that provides nutrition information for a single serving of a food or meal that does not specifically state serving size provided omission of this information does not result in labeling that is false or misleading. For example, if a menu lists the items available in a restaurant followed by a description of the food or meal and information on the fat and calorie content of the food, consumers could reasonably expect that the nutrient content information is declared on a per serving basis, and they will be able to relate this information to the quantity of food they are served.

On the other hand, there may be situations in a restaurant where consumers would not have an appropriate frame of reference for nutrition information unless the serving size used as a basis for the information is specified, for example, when a food is available in more than one serving size (e.g., soup sold by the cup and by the bowl) or when serving size varies (e.g., items from a self-service soup and salad bar where the consumer controls portion size). Furthermore, if nutrition labeling is presented in a format that has requirements for declaring serving size (e.g., Nutrition Facts), nutrition labeling must contain all required elements of the chosen format.

23. **Should a restaurant provide nutrition information on a "per serving" basis, or can the information be declared by other units or measures, such as "per item" or "per unit?" For example, if a restaurant sells whole pizza and pizza by the slice, how should nutrition information be declared?**

Answer: Generally, nutrition information should be presented on a per serving basis. Nutrition information on a per unit basis could be appropriate when a single unit may also be a single serving. However, the basis for the information must be clearly communicated to consumers.

It is especially important that the basis be declared when a food is available in more than one size serving (e.g., pizza that is available whole and by the slice), or soup that is available by the cup or by the bowl. The restaurant may provide additional information, such as "8 slices per medium 16-inch pizza, 1 slice contains..." to help consumers put nutrition information in context.

Conversely, it would be misleading to present the information on a per item basis when a serving generally contains more than one item of the food, for example, if a single serving of cookies contains more than one cookie.

24. **Can a restaurant provide nutrition information on a per item basis when the item is significantly larger than FDA's RACC for the food? For example, the RACC for muffins is 55 g. If a restaurant serves a muffin that weighs 165 g (three times as big as the RACC) can it still treat the muffin as a single serving?**

Answer: If a unit weighs 200 percent or more of the RACC set out in 21 CFR

101.12(b), it may be labeled as a single serving provided it is reasonable to expect that the food would be consumed in a single sitting. For more information on RACCs, see chapter 7 in the Food Labeling Guidelines.

25. **For packaged foods, the actual amount of naturally occurring vitamins, minerals, and protein must be at least 80 percent of the values that are declared on the label, whereas the actual calorie, carbohydrate, and sodium contents may not exceed the labeled values by more than 20 percent. Will FDA apply these same compliance criteria to the nutrient content information declared on labeling for restaurant foods?**

Answer: No. The above compliance criteria (21 CFR 101.9(g)) were established to account for natural variations in the nutrient content of commercially manufactured and packaged foods that are subject to chemical analysis to determine compliance. These criteria ensure that values declared in the Nutrition Facts panel for nutrients such as vitamins and minerals are not over-declared, and that nutrients such as calories and fat are not under-declared, compared to actual amounts that are determined by chemical analyses. The standard that restaurant foods must meet is that a restaurateur has a "reasonable basis" for believing a claim or other nutrition information is valid. Thus, FDA will not subject restaurant foods to chemical analysis to determine whether nutrient levels are properly declared. Rather, FDA will be assessing whether the restaurant's basis for a claim or other nutrition information is, or is not, reasonable. For example, if a restaurant claims a meal is "low fat," FDA would look at the recipe, calculations, and any other information used by the restaurant in determining whether the meal meets the definition of "low fat" (i.e., that it contains no more than 3 g fat per 100 g of food).

26. **Can a restaurant provide nutrition information for different components of a single food or meal separately? For example, can it provide one set of nutrient content information for a salad and a second set of information for the salad dressing if the dressing is served on the side?**

Answer: Nutrition information for different components of a food or meal can be presented separately when the components are served separately (e.g., for a sauce or dressing served on the side), or where the components are separate entities (e.g., a steak, baked potato, and green vegetable) even if the components are served together. It could be misleading, however, to present nutrition information separately for mixed components where the consumer could not reasonably be expected to separate them (e.g., if the dressing is served on the salad).

IV. CONTEXT OF CLAIMS AND COVERAGE BY THE NLEA

Nutrient Content Claims:

27. **What is a nutrient content claim? Could you provide some examples?**

Answer: A nutrient content claim is a statement about a food product that directly, or by implication, characterizes the level of a nutrient in the food (21 CFR 101.13(b)). Thus, nutrient content claims include direct statements about the level (or range) of a nutrient in a food (e.g., "low sodium," "reduced fat," or "contains 100 calories"). An implied nutrient content claim is any claim that: (1) describes the food, or an ingredient in the food, in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "no tropical oils") or (2) suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices when the claim is made in conjunction with an explicit nutrient content claim (e.g., "healthy, contains 3 grams of fat").

28. Would use of terms such as "Nutritious," "Wholesome," "Best choice," or "Good for you" on the label or labeling of a food subject the food to the claims requirements?

Answer: It depends on the context in which the term is used. When a term such as "Wholesome" or "Nutritious" is used in a context that does not render it an implied claim (e.g., "Nutritious foods, prepared fresh daily" or "Made with wholesome ingredients"), it is not subject to the claims requirements. On the other hand, FDA may consider the term to be used in a nutritional context if it appears in association with an explicit or implicit claim or statement about a nutrient. In statements such as "Nutritious, contains 3 grams of fiber," "Best choice, contains 200 mg sodium," or "Good for you, contains 5 grams of fat," the terms are implied nutrient content claims and the foods bearing the claims must meet the requirements for a claim defined by FDA for the nutrient that is the subject of the claim (21 CFR 101.65(d)(1)). For example, a food bearing the claim "Good for You, contains 5 grams of fat," would have to meet the requirements for one of the fat claims, defined in 21 CFR 101.62 (e.g., "low fat") if it is to not misbrand the food.

29. What are the requirements for a restaurant food and its labeling when the food bears a statement about the amount or percentage of a nutrient in the food?

Answer: Statements about the amount or percentage of a nutrient in a food (e.g., "10% protein" or "less than 3 grams of fat per serving") may be made without further qualification if the food meets the definition for a claim (i.e., if the food is "low" in, "reduced," or a "good source" of the subject nutrient (21 CFR 101.13(i) and 21 CFR 101.62(b)(6)). If the nutrient content of a food is not consistent with the definition of a claim, the food may still bear such a statement characterizing the level of a nutrient provided the statement is followed by a disclaimer, e.g., "Only 200 mg sodium, not a low sodium food." If the statement does not in any way qualify the level of a nutrient (e.g., "100 calories" or "5 grams of fat"), a disclaimer is not required.

30. Section 101.10 provides that nutrition labeling for restaurant foods may be presented in a statement such as "low fat, contains less than 10 grams of fat." Can a food that does not qualify for a claim provide nutrition information using a similar statement, e.g., "this meal contains less than 20 grams of fat?"

Answer: No. As stated in response to the preceding question, phrases such as "less than (X amount of nutrient)" are implied claims and can only be used for a food that meets the definition of a claim. Statements such as "contains less than 10 grams of fat" can be used in situations where, according to a restaurateur's reasonable basis determination, a food or meal meets the criteria for a claim (e.g., "low fat") but where he/she may not know the exact amount of the nutrient present. When a restaurateur is presenting nutrition information for a food that does not meet the definition for a claim, and the nutrient values determined using a reasonable basis include some variability (e.g., due to hand assembly of food items), he/she may wish to say "approximately" to indicate that the nutrient values may not be precise.

Furthermore, depending on the context in which it is used, the term "contains" may itself be a nutrient content claim. A statement such as "contains fiber" is a claim that a food is a "good source" of fiber (See Appendix B of the Food Labeling Guide). However, in a statement that includes a quantitative declaration (e.g., "contains 2 grams of fiber"), the amount of fiber in the food is characterized by the quantitative declaration, "2 grams," and the term "contains" is a simple verb, not a nutrient content claim.

31. Can a restaurant provide information on "percent calories from fat" for a restaurant food or meal?

Answer: General dietary guidelines recommend a diet that derives 20-35% of calories from fat. Because a meal is comprised of a number of items from different food groups, and because it contributes a significant proportion of the daily diet, FDA would not object to labeling that provides information about percent calories derived from fat in a meal.

Conversely, FDA stated in the claims final rules that this information (e.g., percent calories from fat) would not be useful for individual food items. The agency is concerned that, because a diet that is consistent with dietary guidelines may be comprised of a variety of foods, highlighting percent calories from fat for individual food items may be misleading. Consequently, FDA discourages labeling that presents fat and calorie content as "percent calories from fat" for individual food items.

32. Can a restaurant call an item "relatively low fat," "very low fat," "extra light," or "almost fat free?"

Answer: No. Only those claims, or their synonyms, that are specifically defined in the regulations may be used (Appendix B of the Food Labeling Guide). All other claims are prohibited (21 CFR 101.13(b)).

33. Would use of the term "Fresh" trigger the nutrition labeling requirements of the NLEA?

Answer: No. FDA addressed the use of the term "Fresh" to describe foods that are

unprocessed or unpreserved in the same issue of the Federal Register in which the claims final rules appeared. However, "Fresh," as defined in 21 CFR 101.95, is not a nutrient content claim or a health claim and use of the term does not trigger nutrition labeling requirements.

34. Could FDA elaborate on the types of statements about ingredients in a food that would be an implied nutrient content claim?

Answer: A statement highlighting the presence or absence of an ingredient, where the ingredient is associated with the level of a nutrient, would be an implied nutrient content claim. Long recognized ingredient-nutrient relationships include: sugar and calories, oils and total fat, tropical oils and saturated fat, and whole grain or bran and dietary fiber. The statement "Contains oat bran," for example, implies that a food is "a good source of dietary fiber."

35. I make a pizza with "low fat cheese." Even though my pizza is not "low fat" can I make a nutrient content claim about the cheese?

Answer: The agency considers a product that makes an express claim ("free," "low," "good source," or "high") about an ingredient in a product to be an implied relative claim about the product itself. For example, a claim that a pizza is "made with low fat cheese" is an implied claim that the pizza is at least "reduced in fat" compared to a similar pizza. Such a claim would be prohibited if the product did not meet the criteria for the relative claim ("less" or "more" of a nutrient) that it implied. In addition, for such an implied relative claim, the accompanying information required for relative claims would also be required (e.g., 25% less fat than regular pizza, contains ____g fat, regular pizza contains ____g fat). However, consistent with FDA's flexible approach, the agency would not object to the quantitative comparison information appearing on nutrition labeling if the labeling that bears the claim does not have sufficient space to accommodate the full statement (21 CFR 101.65(b)).

36. Would a statement such as "contains no dairy ingredients" be an implied claim?

Answer: A statement that is not presented in a nutrient context, such as statements to facilitate avoidance (e.g., "contains no dairy ingredients"), information about characterizing ingredients or ingredients perceived to add value (e.g., "contains real butter"), and ingredients that do not serve nutritive purposes (e.g., "no preservatives") would not be an implied nutrient content claim (21 CFR 101.65(b)).

37. When would a statement about the way a food is prepared be an implied nutrient content claim?

Answer: The statement would be an implied nutrient content claim if it highlights a preparation method that affects the nutrient content of a food (21 CFR 101.65). For example, "made only with vegetable oil" implies that, because vegetable oil was used instead of animal fat, the food is "low in saturated fat" or "cholesterol

free." On the other hand, a statement about a preparation method that affects the character of a food but that does not characterize the nutrient content of a food (e.g., "made with fresh fruit" or "prepared fresh daily") would not be an implied claim.

Terms such as "broiled," "fried," or "steamed" would not subject a food to the nutrient content claims requirements if they are part of a food's identity statement (e.g., "baked potato," "steamed shrimp," or "fried zucchini"), or are used solely to identify different categories of food. In addition, labeling that bears a statement such as "available broiled or fried" in the context of providing optional preparation methods for a food would not, by itself, be an implied nutrient content claim. However, a statement such as "donuts, baked not fried" that highlights the preparation method in a way that consumers may assume that the food, because of the way it was prepared, has less or more of a nutrient would be an implied claim.

38. If the name of a restaurant establishment contains a term that may, in some contexts, be an express or implied claim (e.g., "Cafe Lite" or "Skinny Haven"), would FDA require the foods sold in the establishment to meet the definition for a claim, and if so, would all the foods sold in the establishment be expected to comply?

Answer: The name of an establishment is not necessarily a claim for the foods sold by the establishment. If, for example, "Cafe Lite" is the name of a restaurant, but the term is not being used to describe the foods sold by the restaurant (e.g., the name of the restaurant is not printed on labeling that describes the selections offered by the restaurant), it would not be a claim for the food. Further, if the name of the restaurant appears on labeling but is used in a context other than as a nutrient content or health claim (e.g., use of the term "Lite" to describe smaller portions or "Skinny" because it is the proprietor's nick-name), the term would not be a claim subject to the NLEA.

Conversely, if the name of the establishment is used to describe the foods served in the restaurant and the term is used in a nutrient context (e.g., "Cafe Lite" appears prominently on labeling and is accompanied by fat or calorie content claims), the foods that bear the claim must be clearly distinguishable from food items that do not. For example, selections that meet the requirements for a "light" claim may be highlighted by the use of a symbol or different type style and a footnote explaining that the highlighted items are light in fat or calories, or sodium.

39. What if a restaurateur is having difficulty determining whether a statement is an implied claim?

Answer: Some statements clearly are implied nutrient content claims while other statements clearly are not. Situations where the agency has been able to determine that a statement would or would not constitute an implied claim are set out in 21 CFR 101.65. In many cases, however, whether a label statement is an implied claim can only be determined on a case-by-case basis, considering the entire label and the context in which the claim is made. In determining whether a statement is, or is not, an implied claim, FDA would consider both the restaurateur's intent and

the consumer's likely perception of a statement.

Health Claims:

40. What is a "Health Claim?"

Answer: A health claim is a reference on the label or in the labeling of a food that directly, or by implication, including 'third party' references, written statements, symbols, or vignettes, characterizes the relationship of a nutrient or substance to a disease or health related condition (21 CFR 101.14(a)(1)). While a nutrient content claim refers to a level or range of a nutrient in a food, a health claim includes two elements, i.e., a reference to a nutrient or substance and a reference to a disease or health related condition. Labeling that links a specific food to a statement such as "Heart Healthy" contains both the substance element (reference to a specific food) and the disease-condition element (implied reduction in risk of heart disease) of a health claim. Health claims may be used on the label or labeling of a food only if claims about the nutrient-disease relationship involved have been authorized by FDA in a regulation.

41. What is an implied health claim?

Answer: Implied health claims include those statements (e.g., "Heart Healthy"), symbols (e.g., a heart symbol), vignettes, or other forms of communication that suggest that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition (21 CFR 101.14(a)(1)).

42. When would a heart symbol on restaurant labeling be an implied health claim?

Answer: Whether a heart symbol is an implied health claim will depend on the context in which it is used. FDA advises that most of the perceptions about heart symbols fall under the regulatory regime of a health claim. For example, use of a heart symbol in association with a nutrient content claim (e.g., a claim about saturated fat or cholesterol) could imply that the food, because of its nutrient content, may be useful in reducing the risk of developing a disease or health-related condition, specifically, heart disease. Use of a heart symbol or similar logo in this context would trigger the health claims requirements that a food meet the definition of an approved claim, and that it bear nutrition labeling. Further, use of a heart symbol alone (i.e., in the absence of a statement explaining its use), could be misleading.

Alternatively, when a symbol is clearly being used in a context other than to highlight nutrient or health-related benefits of a food (e.g., a heart symbol followed by a statement such as "You'll love our home-made pies and cakes!") it would not be an implied claim. Further, a heart symbol may be used to identify items that are consistent with the dietary recommendations of a health professional association when labeling bears a statement explaining such use (e.g., the symbol is repeated in a footnote followed by a statement such as "these items are consistent with AHA guidelines," without triggering the claims requirements

provided labeling does not bear another statement, phrase, symbol, or logo that would cause the heart symbol to be a claim in the context of the entire label (see question 55).

43. What are the nutrient-content requirements for a food to bear a health claim?

Answer: Generally, a serving of the food or meal must contain less than the specified levels of four disqualifying nutrients: fat, saturated fat, cholesterol, and sodium (21 CFR 101.14(a)(5)).

Generally, without fortification, the food must contain at least 10 percent of the Daily Value for at least one of the following six nutrients: vitamin A, vitamin C, calcium, iron, fiber, or protein.

In addition to these general requirements, the food must meet the specific criteria listed in the regulation for each claim. For example, a food bearing a claim that links a diet low in total fat to the risk of some cancers (21 CFR 101.73) must also meet the definition for "low fat."

44. What are disqualifying levels?

Answer: Disqualifying levels are those levels of total fat, saturated fat, cholesterol, or sodium in a food above which the food will be disqualified from making a health claim (21 CFR 101.14(a)(5)). For individual food items, these levels are per Reference Amount Customarily Consumed and per serving (or, in the case of foods with RACCs of 30 grams or less or 2 tablespoons or less, per 50 grams). Values for meals and main dish items are per serving. Any one of these levels (e.g., per RACC or per serving), will disqualify a food from making a health claim.

45. Would a claim such as "Heart Healthy" or "Heart Fest" fulfill the informational requirements for a health claim?

Answer: No. An implied claim such as "Heart Healthy" does not contain the required elements. Terms such as "Heart Healthy" would need to be accompanied by additional information to be sufficiently informative.

46. If additional information is needed to make a claim such as "Heart Healthy" fully informative, how should it be presented, and where must it appear relative to the implied or abbreviated claim?

Answer: The additional information should appear adjacent to the implied or abbreviated claim. If a number of foods bear an abbreviated claim, the additional information, (e.g., the full health claim), may appear adjacent to each abbreviated claim or adjacent to the most prominent claim. If the foods that bear an abbreviated health claim are grouped together in a box or other section of the labeling, the full health claim may appear once within that section.

Alternatively, where any graphic material or statement that constitutes an express or implied claim (e.g., "Heart Healthy"), the abbreviated claim may be followed in immediate proximity by the reference statement, "See _____ for information about the relationship between _____ and _____" informing consumers where the additional information may be found (21 CFR 101.14(d)(2)(iv)). Thus, the information required to be in the full health claim may appear elsewhere on the same or different labeling as the implied claim. In a restaurant, labeling that bears an abbreviated health claim may bear a statement such as "Ask your server for information about the relationship between (insert nutrient or substance) and (insert disease or health-related element)" if the full claim appears in labeling (e.g., a brochure or notebook) that is used by a restaurant to convey nutrition information.

47. Can a restaurant communicate useful nutrition-related information to consumers in a way other than a nutrient content or health claim?

Answer: Yes. Restaurants may offer alternative selections whose value in the diet may be recognized without elaboration, e.g., raw vegetables, steamed vegetables, a grain dish, a fresh fruit plate, or pasta with a tomato based sauce instead of a cream sauce. Optional preparation or serving methods may also be highlighted by statements such as "may be prepared with half the oil on request," "smaller portions," or "dressings and sauces available on the side," provided the statement about an ingredient or preparation method does not make an implied claim about the nutrient content of the food.

48. A number of food service establishments provide foods for special dietary use (e.g., health resorts that serve food that is useful in reducing or maintaining body weight or hospitals that provide food to help regulate sodium intake). Would such food be subject to the nutrient content claims requirements if its label or labeling bears a statement about the use of the food in a special diet?

Answer: It depends. There is a separate set of requirements for foods for special dietary use in 21 CFR part 105. A claim made solely to identify a food that meets a particular dietary need that exists by reason of a physical, physiological, pathological, or other condition as described in part 105 would generally not be a nutrient content claim (21 CFR 101.65(b)(6)). Thus, a claim such as "Use as part of a weight reduction program" that identifies the special diet of which the food is intended to be a part would not, by itself, be a nutrient content claim.

However, if the claim about the use of the food in a special diet is used in a context that highlights a nutritional aspect of the food that is relevant to the general population (e.g., it is accompanied by a "low sodium" or "low calorie" claim), the food and its labeling would be subject to the nutrient content claims requirements.

49. Are statements that are not covered by the NLEA subject to any other requirements?

Answer: Yes. Statements outside the coverage of the NLEA are still subject to the requirements in the law that they must be truthful and not misleading.

Dietary Guidance:

50. What are "dietary guidelines?" How does dietary guidance differ from a nutrient content claim?

Answer: Dietary guidelines are general dietary guidance for good health made publicly available by recognized governmental (e.g., the U.S. Surgeon General, the U.S. Department of Agriculture, the Department of Health and Human Services, the National Cancer Institute, and the Centers for Disease Control and Prevention), or private health professional organizations (e.g., the National Academy of Sciences, the American Dietetic Association, and the American Heart Association). Dietary guidance provided by third parties would need to be consistent with the recommendations of recognized dietary authorities and the current Federal Government's *Dietary Guidelines for Americans*. *Dietary Guidelines* generally promote moderate intake of nutrients such as sodium, fat, and saturated fat and increased consumption of grains, fruits, and vegetables. Dietary guidance is a group of general recommendations based on a total diet (e.g., "Eating a variety of 5 fruits and vegetables a day is an important part of a healthy diet," "Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol, may help reduce the risk of heart disease and certain cancers").

Conversely, a nutrient content claim is a claim about the nutrient content of a particular food (e.g., "low fat, this meal contains 10 grams of fat"). Claims about a food that suggest that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and that are made in conjunction with an explicit claim or statement about a nutrient (e.g., "Healthy, contains 3 grams of fat") are implied nutrient content claims (21 CFR 101.65(d), see Appendix B of the Food Labeling Guide).

51. Can a restaurant say that an individual food or meal meets dietary guidelines when guidelines are based on recommendations for a total diet?

Answer: It depends, in part, on the specific recommendations of the particular group. The Federal Government's 2005 *Dietary Guidelines for Americans*, for example, recommend a diet with "moderate calorie intake, between 20-35 percent of calories from fat, less than 10 percent of calories from saturated fat, less than 300 mg cholesterol per day, emphasis on vegetables, fruit, and grain products, and minimal use of added sugars, *trans* fats, and sodium." While a variety of foods may make-up a total diet, it may also be possible to identify a food or meal that can be part of a diet consistent with these recommendations.

52. The recommendations in the dietary guidelines of a number of professional health organizations include specific levels for intake of a nutrient based on total daily consumption. For example, the American Heart Association guidelines include the

recommendation that Americans consume no more than 2,300 mg of sodium and no more than 300 mg of cholesterol per day. How can nutrient values for recommended minimum or maximum daily intake be related to an individual food or meal?

Answer: When converting a value based on daily intake to a value that is appropriate for an individual food or meal, the recommended daily intake must be divided by an appropriate factor. Consumers generally eat three meals and several snacks a day. Because a single meal constitutes approximately 25% of the daily diet, dividing the daily value for a nutrient by a factor of 4 may be appropriate for determining the contribution of the level of that nutrient in a single meal towards a daily diet. Thus, a meal containing no more than 575 mg of sodium (2,300 mg/day X ¼ daily food intake = 575 mg) could be incorporated into a diet consistent with the American Heart Association's guidelines for sodium. A recommended value for daily consumption would need to be divided by a larger number, such as 8 for a main dish and 16 or 20 for an individual food item since a greater number of individual foods may be consumed in the course of a day.

53. **Is there a simple way to identify foods that should not be highlighted as part of a diet consistent with dietary guidelines?**

Answer: Yes. If a food contains a nutrient at a level that exceeds the disqualifying levels in the general health claims requirements set out in 21 CFR 101.14(a)(5), it would be difficult for a consumer to incorporate such food into a diet consistent with generally accepted guidelines for a healthy diet. Although a healthy diet is composed of a variety of foods with different nutrient profiles and could include such foods, a claim that such a food would be a useful part of a diet consistent with dietary recommendations would be misleading if the food that bears the claim is not helpful in reaching dietary goals.

54. **Can a restaurant make a claim that a meal "is consistent with dietary guidelines" if the nutrient profile of the meal is consistent with some, but not all, of the guidelines established by a particular organization? For example, can a restaurant say a meal is consistent with dietary guidelines based on the fat content of the meal without regard to the level of other nutrients, such as sodium and cholesterol?**

Answer: Generally, if a meal bears a claim that it is consistent with the dietary guidelines of a health professional organization, its nutrient content must be consistent with all the parameters of the guidelines of the organization. If the level of another nutrient in the meal (e.g., sodium) is not consistent with the dietary guidelines referred to, a claim that the meal is consistent with dietary guidelines would be misleading. (While statements about general dietary recommendations do not by themselves trigger specific nutrition labeling requirements, FDA would expect that a restaurant have available, as part of its reasonable basis for believing a food is consistent with dietary recommendations, information on the level of all nutrients associated with the recommendations of the organization.) Furthermore, statements that single out recommendations for a particular nutrient (e.g., "meets dietary guidelines for fat"), may be a claim about the nutrient content of the food (and therefore subject to the requirements for claims), rather than a statement offering general dietary guidance.

55. Could FDA elaborate on how restaurants can present information that a food or meal meets general dietary guidelines without making a nutrient content claim or a health claim?

Answer: Statements that a food or meal meets the dietary guidelines of a health professional organization or other recognized dietary authority will be considered dietary guidance and not a nutrient content claim or health claim, provided the statement is limited to general dietary guidance and does not characterize the level of a nutrient in the food (21 CFR 101.13(q)(5)(iii)). The Centers for Disease Control and Prevention's recommendation, for example, that "Eating a variety of fruits and vegetables a day is an important part of a healthy diet," is general dietary guidance.

Restaurants may use a heart symbol to indicate food items that are consistent with the recommendations of a health professional organization such as the American Heart Association. However, information from such programs presented in labeling in a context that includes an explicit or implicit health claim (e.g., a statement such as "meets (insert association name) guidelines for a 'Heart Healthy' diet" or "meets the National Cancer Institute recommendations for fiber") will subject the food to the health claims requirements.

If a food bears a claim, it must comply with the requirements for the claim. If a restaurant wants to provide information as dietary guidance and not a health claim, it should not give undue emphasis to terms or symbols that could be an implied claim. Restaurants are encouraged to use alternative terms or symbols (e.g., a star or a check mark instead of a heart), to identify items that may not comply with the health claims requirements. If the name or logo of a third party reference is likely to be an implied claim when seen in conjunction with an individual food or meal, and the food or meal does not comply with the requirements for the claim, care should be taken to separate the reference from individual foods. It may be possible, however, for labeling to bear a statement such as "This restaurant has been a paying member of (insert program name) since 1994" provided such statement refers to the establishment, not a food, and it is less prominent (in size, type style, and placement) compared to other statements that refer to the food.

56. Would a statement that a meal can be part of a diet that is consistent with the dietary guidelines of a health professional organization be regulated as a health claim if the name of the organization includes a reference to a disease or health-related condition?

Answer: It depends. Reference to the organization will be regulated as a health claim if, within the context of the total labeling, it implies a relationship between a nutrient or substance and a disease or health-related condition. Conversely, some groups have a history of providing general dietary guidance for good health such that consumers would not automatically assume that the name of the organization or its logo implies association with the disease-related element of a health claim. Thus, reference to these groups and their guidelines would not constitute a health

claim provided that the guidelines are general dietary recommendations (compared to dietary recommendations for individuals with a specific disease or health related condition) and reference to the organization contains no other reference to a substance or health-related condition.

57. Can labeling that identifies items that are consistent with general dietary guidelines also provide consumers with nutrition-related information about the guidelines? Would this information be considered a nutrient content claim?

Answer: Restaurant labeling may provide information about the guidelines of a professional health organization. Whether the information is regulated as a nutrient content claim or as dietary guidance will depend on the context in which it is presented. If nutrient information is directly linked to a particular food or meal (e.g., "this meal derives no more than 30% of its calories from fat"), the information would be a nutrient content claim (see question 54). However, if the information merely presents the guidelines of a health professional organization without making a statement about the nutrient content of a particular food, the information would not be a nutrient content claim. For example, labeling that highlights items that may be part of a diet that is consistent with all guidelines of a particular group may bear a footnote stating, "Highlighted items are consistent with the general dietary recommendations of (insert name of health professional organization). These guidelines are (describe all nutrient recommendations that comprise the group's guidelines)."

58. What is a 'third party' reference?

Answer: It is a reference on product labeling or advertising, made through a name or logo, linking a product to a person or organization that is independent of the product's manufacturer, seller, or distributor (the first party), or the consumer (the second party). The third party may be a State or local health department or consumer service agency, health professional organization, registered dietician, chef, celebrity, or other independent person or organization.

59. If labeling bears a third party endorsement of a food or meal, and a financial contribution to the third party is a mandatory criterion for the endorsement, does the labeling that bears the endorsement need to disclose that the endorsement was made for compensation?

Answer: Yes. Failure to reveal that the endorsement required that compensation be made would be misleading. Labeling that bears the endorsement should bear a disclosure statement such as "A fee was paid to (insert name of program)" or "A paying member of (insert name of program)" in close proximity to the claim.

60. Many restaurants and third party programs use the term "healthy," (e.g., "Healthy Selection" or "Heart Healthy"), to describe foods. How will FDA regulate this term?

Answer: The term "Healthy" has a wide variety of meanings, depending on the context in which it is used. When the term (or any derivative of the term, e.g.,

"health," "healthier," or "healthful") appears in association with an explicit or implicit claim or statement about a nutrient (e.g., "Healthy, contains 3 grams of fat"), it is a nutrient content claim, and the food must meet the requirements for the claim (21 CFR 101.65(d)(2)) (Appendix B of the Food Labeling Guide).

"Healthy" in a phrase such as "Healthy Heart" or "Heart Healthy" could be an implied health claim about heart disease (see question 40). Alternatively, the statement "Eating a variety of fruits or vegetables a day is a good way to a healthy lifestyle" is not a health claim because it provides only general dietary guidance (i.e., it does not cite any particular health related condition nor does it refer to a particular food or substance).

Use of Undefined Terms and Terms or Symbols in a Different Context (21 CFR 101.13(q)(5)(iii)):

61. A number of restaurants identify items with terms such as "Lite Fare" to indicate that the portion size of the food is smaller than normal. Must these foods meet FDA's definition for "Light" or "Lite?"

Answer: It depends. Statements such as "Light Fare," "Light Bites," or "Light Entrees" will not be considered nutrient content claims provided that they do not characterize the level of a nutrient and the labeling that bears the claim also explains how the term is being used. For example, the term "Lite Fare" may be marked with an asterisk referring consumers to a statement explaining that the term means smaller portions. The explanatory statement must be located in reasonable proximity to the term (e.g., at the bottom of the same section of labeling that contains the "Lite Fare" term and the foods it describes).

62. Does this mean that claims on restaurant foods are exempt from the NLEA requirements, or that the restaurant may define a claim differently from FDA's requirements, so long as the labeling provides an explanatory statement for the claim?

Answer: No. An explanatory statement can not be used to exempt a term or symbol from the claims requirements when the term or symbol is an explicit or implied claim. Further, an explanatory statement is not sufficient to render a term or symbol not misleading when the term or symbol is used in the context of a nutrient content claim or a health claim, and the food does not meet the requirements for the claim. A restaurant cannot, for example, make a "low fat" claim for a food that contains more than 3 grams of fat per RACC (or per 100 grams for meals and main dish items), even if the labeling that bears the claim also contains a statement explaining the restaurant's definition for the claim.

63. Many restaurants readily substitute meal components at the request of consumers, e.g., fried fish for baked fish, or French fries in place of a salad. How would FDA regulate a meal that complies with the requirements for a claim before substitution but that does not qualify afterwards?

Answer: It depends. If a restaurant makes a claim about its selections (e.g., "build your own low fat meal, selections contain less than 3 grams of fat"), and allows consumers to select meal components from different categories, all combined components must meet the requirements for the claim. If different combinations of foods do not meet the definition for a claim, the restaurant should not make a claim for those combinations. However, it may still make claims for the individual food items that meet the requirements for a claim. In addition, if a consumer chooses to mix foods from categories for which the restaurant makes a claim with foods from groups for which the restaurant does not make a claim, the meal with substituted components would not need to meet the requirements for a claim so long as labeling did not make an express or implied claim for that combination. For example, if a restaurant claims a salad plate, (e.g., tuna salad, fruit, and cottage cheese), is a "low fat" meal, all items on the plate must, in combination, meet the definition of "low fat." However if a consumer orders the salad plate but decides to delete the cottage cheese and order French fries instead, the meal is a new and different combination of foods from that for which the restaurant made a claim.

64. Where can I find more information on FDA's requirements for claims?

Answer: Copies of FDA's regulations are found in Title 21, Code of Federal Regulations, parts 100-169. This book may be purchased from the U.S. Govt. Print. Off., Supt. of Docs., Mail Stop: SSOP, Washington, DC 20402-9328 (Order # 869-038-00000-8 GPO for paper). The claims regulations are in part 101. Copies of the CFR may also be purchased from other U.S. Government printing offices throughout the United States and are available online at http://www.access.gpo.gov.

Determining the Nutrient Content of a Restaurant Food:

65. When making a claim, do I have to have my food analyzed by a lab to determine its nutrient content?

Answer: No. A restaurant food, including restaurant-type foods described in 21 CFR 101.9(j)(3), may bear a nutrient content claim or health claim provided the restaurateur has a "reasonable basis" for believing that the food meets the definition for the claim. If a restaurateur labels a food "low fat," for example, he or she must have a reasonable basis for believing that the food complies with FDA's definition for "low fat" (i.e., that it contains no more than 3 g of fat per RACC or, in the case of meals and main dishes, no more than 3 g of fat per 100 g) (see question 25).

66. What nutrient information sources can be used as a reasonable basis for determining the nutrient content of a restaurant food? Can nutrient information sources be combined?

Answer: Nutrient levels may be determined based on reliable nutrient data bases, cookbooks, or analyses, or by other reasonable bases that provide assurance that

the food or meal meets the requirements for the claim (21 CFR 101.13(q)(5)(ii)). Additional sources of nutrition information include: USDA's Handbook No. 8 and current FDA's guideline on nutrient levels in seafood and information on the nutrient content of raw fruits and vegetables, (published in conjunction with FDA's regulation on the voluntary labeling of raw fruits and vegetables). Nutrition information for foods manufactured for institutional or restaurant use may also be available from the manufacturer or may, in some cases, be provided on the food's labeling. Such information on nutrient content of ingredients can be used along with the restaurant's recipe to calculate the nutrient content of the prepared food. Sources of nutrient information may be combined (e.g., merging data base values with information from ingredient suppliers) so long as the combined sources of information are still valid.

67. Restaurants often need to modify recipes when a recipe is scaled-up from a home kitchen recipe to provide a larger number of servings for institutional use. Can a restaurateur still use the nutrient information in a consumer cookbook as a basis for a claim on the finished food if the proportion of some ingredients to others is altered during scale-up?

Answer: It depends. The claims criteria generally require that a nutrient be present at "no more than" or "no less than" a given level. Thus, a restaurateur may be able to determine that a food prepared using a modified recipe still meets the criteria for a claim without knowing the precise amount of the nutrient that is present in the finished food. For example, a restaurateur may reduce the proportion of salt and spices in a recipe for a "low sodium" soup during scale-up while the proportion of other major ingredients remains the same. The restaurateur may no longer know the exact sodium content of the food (i.e., the sum of sodium from added salt and that contributed by the other ingredients). However, assuming the nutrient values provided with the original recipe meet FDA's definition of "low sodium," the fact that changes during scale-up reduced, rather than increased, the primary sodium containing ingredient, would support a reasonable basis determination that the finished food is "low sodium."

However, if a recipe is altered in such a way that the restaurateur is not able to determine the effects of the change on the nutrient content of the finished food, the nutrient information based on the original recipe would no longer serve as a "reasonable basis" for believing the finished food meets the definition for a claim.

68. Will FDA require prior approval for a restaurant food to bear a claim?

Answer: No. FDA does not have the authority to require prior approval of restaurant labeling that bears a nutrient content claim, health claim, or other nutrition information.

69. Will restaurants be required to have claim bearing foods "certified" by a third party or an independent dietary professional?

Answer: No. FDA has provided broad flexibility in establishing the "reasonable

basis" criterion for restaurant foods. Thus, while some restaurateurs may choose to work with a third party to modify recipes or revise labeling, there is no requirement to do so. Restaurants should be able to make their own determinations once they are familiar with the requirements.

70. Is FDA approving or recommending data bases for use as a restaurant's "reasonable basis" for a claim?

Answer: FDA has not approved, nor is it recommending, any specific data base for use in restaurants. Each restaurant must assess its own information needs and capabilities to ensure that the data base or other "reasonable basis" for the claims it makes is sufficient to support a claim. Assistance may be available through the following sources: trade and professional associations, trade publications, private consultants, and colleges and universities.

Adherence to the "Reasonable Basis":

71. Many food service items are partially or wholly processed when they are purchased for use in a restaurant or similar establishment. Thus, it may be difficult for the restaurant to keep track of the sodium content of foods. It may also be difficult for a restaurant to monitor the use of sodium in the cooking process and to develop recipes for "low sodium" foods that taste good. How will these problems be addressed in implementing the new requirements?

Answer: FDA does not intend to impose an unrealistic regime (e.g., to require exacting measurements or strict portion controls) in restaurants. However, the agency is requiring that a restaurant have a reasonable basis for believing that a food meets the nutrient requirements for a claim, and that it be able to provide reasonable assurance that the preparation of the food adheres to the basis for the claim. If a restaurateur has no knowledge of, or control over, the sodium content of a food, or some other aspect of its nutrient content, he/she should not attempt to make a sodium content or other claim about the nutrient levels in that food.

72. Many restaurants do not have, or do not use, scales. Consequently, wouldn't a criterion such as "no more than 30 percent of calories from fat" be more appropriate for a low fat claim on a restaurant food compared to weight based criteria?

Answer: No. First, the "no more than 30 percent of calories from fat" criterion does not, by itself, ensure that a food is low in fat. Second, in order to have a reasonable basis for believing that a food derives no more than 30 percent of its calories from fat, a restaurateur needs to have sufficient information on the types and quantities of ingredients used in the food to determine both its fat and calorie content. The same information used to calculate percent calories from fat (a criterion for a low fat claim on meals and main dishes) can be used to calculate the amount of fat per RACC or, in the case of meals and main dishes, per 100 g of food.

73. To support its basis for a claim, does a restaurant need to weigh every serving of a food and calculate the amount of a nutrient in each serving every time it prepares the food?

Answer: No. A reasonable basis determination only needs to be done once provided portion size is reasonably constant, the restaurant follows a standardized recipe, and the method of preparation adheres to the basis for the claim.

74. What types of actions would invalidate a restaurant's "reasonable basis," and what should a restaurateur do to help ensure this does not happen?

Answer: Restaurateurs will need to employ preparation methods that are sufficiently consistent, including weight and volume measurements, to provide reasonable assurance that the preparation method adheres to the basis for the claim. They must also consider the effects of any addition or substitution of ingredients, or of any change in preparation method, on the level of a nutrient that is the subject of a claim. For example, the nutrient content values that FDA published in conjunction with the voluntary nutrition labeling program for baked fish would no longer apply to fish that is breaded or fried.

It may be necessary for some restaurateurs to develop written standard operating procedures or other kitchen instructions for use by staff to guard against uncontrolled addition or substitution of ingredients. For example, if a "low fat" claim depends on the use of skim milk rather than whole milk, staff should be aware that the food bearing a "low fat" claim may not be made with whole milk. Further, if a food bears a "low sodium" claim based on its containing a limited amount of salt, allowing staff to "salt-to-taste" instead of using measured amounts would contravene the reasonable basis for believing that the food meets the requirements for the claim.

75. How will compliance with the claims requirements be evaluated in a restaurant situation?

Answer: For compliance purposes, FDA will look at the recipe, nutrient information source, and any calculations used by a restaurant as its "reasonable basis" for believing that a food meets the requirements for a claim or other nutrition information. FDA will evaluate whether this information, and the nutrition information provided to consumers, are consistent with FDA's definition for the claim that is used. FDA may also request that a restaurant provide reasonable assurance that the method of preparation used adheres to the restaurant's basis for the claim.

76. Data base analysis reveals that a restaurant food contains 3.3 grams of fat per RACC. Can the food bear a "low fat" claim?

Answer: No. The definition for a "low fat" claim is that the food contains no more than 3 grams of fat per RACC (3.3 g of fat per RACC would be declared as 3.5 g). If the restaurant's reasonable basis determination shows that a food

contains more than 3 grams of fat per RACC, the restaurateur would not have a reasonable basis for believing the food meets the definition of the claim. For more information on rounding guidelines, see Appendix H of the Food Labeling Guide.

77. What are the record keeping requirements for a restaurant that make claims?

Answer: The restaurant must keep sufficient records to provide appropriate regulatory officials, upon request, with information on its "reasonable basis" and with reasonable assurance that the preparation method adheres to that basis. The type and amount of information necessary to support a claim will vary with the type of establishment, the types of food sold, preparation methods, and the types of claims being made. However, the following check list may be helpful:

1. Standardized recipe, including ingredients used and their quantities,
2. Nutrient content data for each ingredient (may include information from the ingredient manufacturer, a reliable data base, or other nutrient information source, or a combination of these; information must include data for the nutrients that are the basis for the claim and may include data for other nutrients,
3. The source of the above data (e.g., the name of the data base, cookbook, etc.),
4. Any assumptions made by the restaurateur or any calculations that were performed that may affect the reliability of the data (e.g., combining data sources, assumed nutrient values, replacing generic or average data base values with values for brands specifically used in the restaurant, etc.),
5. Serving size (total weight) of the finished food or meal,
6. Total amount of nutrient present per RACC, actual serving, or per 100 g of food, as appropriate for the definition of the claim,
7. Evidence of staff awareness that reasonably consistent ingredient measurement and portion control are necessary for foods bearing a claim (e.g., training materials, observation of food preparation methods),
8. Presence and use of a standard operating procedure identifying essential parameters in the preparation of a food bearing a claim (e.g., the use of skim milk instead of whole milk, broiling instead of frying, or the need to measure salt instead of salting to taste), when the method of preparation could affect the basis for a claim.

78. If a restaurant makes a fat claim for a food based on the use of skim milk, for example, does it have to save records to prove that it purchased, and used, an appropriate quantity of skim milk?

Answer: Not necessarily. The requirements in 21 CFR 101.13(q)(5)(ii) require that a restaurant provide reasonable assurances that it adhered to its basis for making a claim. Examples of the types of information that may be useful for a restaurant to provide in support of its basis for a claim are discussed in response to the preceding question. It is unlikely that a regulatory official would require information like the records of ingredient purchases unless he/she had reasonable cause to doubt a restaurant's stated basis.

Reference Amounts Customarily Consumed:

79. What is a "Reference Amount Customarily Consumed (RACC)?" Do restaurants need to alter their serving size to be equal to the RACC?

Answer: The RACC is the amount of a food item customarily consumed per eating occasion as determined by FDA for the purpose of establishing realistic and consistent serving sizes for use in food labeling. RACCs for almost 150 different food categories are set out in 21 CFR 101.12. (RACCs for meat and poultry products are listed in 9 CFR 317.312.)

Restaurants do not need to alter the size of the portions they serve to be the same as the RACC, nor does the serving size used in the labeling for a particular food need to be the same as the RACC. However, in order to make certain nutrient content claims or health claims, an individual food must meet the definition for the claim based on the amount of the subject nutrient in an amount of the food equal to its RACC (e.g., a "low fat" food may contain up to 3 grams of fat per RACC). When a food's RACC is small (i.e., 30 grams or less or 2 tablespoons or less), the food (e.g., a sauce or condiment) must also meet the requirements for the claim based on its nutrient content per 50 grams.

80. How does a restaurant determine whether a food meets the criteria for a claim when the serving size is different from the RACC? Please address soup in your answer.

Answer: The RACC for all types of soup is 245 grams. This value is based on the amount of soup that survey data showed is customarily consumed in a single sitting, i.e., 1 cup, and information from the USDA that the average gram-weight per cup measure for soups is 245 grams.

For some claims (e.g., "free"), the criteria for the claim include the amount of a nutrient per RACC and per labeled (or actual) serving size. In order to bear a "fat free" claim, a restaurateur must have a reasonable basis for believing the soup contains less than 0.5 grams of fat per serving. Nutrition labeling would declare fat content as "0." In order to bear a "low fat" claim, soup may contain up to 3 grams of fat per cup (245 grams) according to the restaurateur's reasonable basis determination. If the same soup is served to consumers in a bowl that holds 50 percent more soup (1.5 cup (367 grams)), the larger serving may contain up to 4.5 grams of fat (i.e., a serving size that is 1.5 times the RACC may contain 1.5 times as much of the subject nutrient).

81. Are the criteria for the claim still based on RACCs when making a relative claim such as "reduced fat?"

Answer: Yes. A "reduced fat food," for example, must contain at least 25% less fat per RACC compared to the reference food. However, for all practical purposes, when the RACCs are the same for both foods (e.g., "regular potato salad" and "reduced fat potato salad"), the comparative information (% fat reduction) may be calculated based on equivalent amounts of each food,

independent of the RACC.

82. What basis do I use when making a claim about the nutrient content of a meal?

Answer: Criteria for the use of claims on meals and main dishes (as defined in 21 CFR 101.13(l) and (m)) are somewhat different from those for individual foods. The criteria for claims for meals and main dishes are based on the level of the nutrient in 100 grams of the food. For example, while a "low fat" individual food contains 3 grams or less of fat per RACC, a "low fat" meal (or main dish) contains 3 grams or less of fat per 100 grams of food. Thus, a "low fat" meal weighing 300 grams (approximately 10 ounces) may contain as much as 9 grams of fat per serving.

Reference Foods

83. Question: What types of claims require identification of a reference food?

Answer: There are two types of nutrient content claims (i.e., relative and absolute claims). A relative claim is a claim about the level of a nutrient in one food compared to another food (i.e., the reference food). When making a relative claim (e.g., "more," "less," "reduced," or "added"), the restaurateur will need to know the level of one or more nutrients in both the food making the claim and in the reference food. Conversely, an absolute claim (e.g., "high," "low," or "free") is based on the level of a nutrient in the food making the claim, and comparison to a reference food is not necessary.

84. Must a restaurant develop recipes for, analyze, and market, a reference food for every food that bears a relative claim?

Answer: No. The reference food may be the restaurant's regular product, or that of another restaurant, that has been offered for sale to the public on a regular basis for a substantial period of time. However, nutrient values for a reference food may also be derived from such sources as a valid data base, an average of top national or regional brands, or a market basket norm (21 CFR 101.13(j)(1)(ii)).

85. Can a restaurant make nutrient comparisons between dissimilar foods in the same category (e.g., comparing two appetizers or two different entrees)?

Answer: It depends on the claim. Claims such as "reduced" may only be used to compare individual food items that are similar (e.g., potato chips to potato chips). However, claims such as "more" or "less" may be used to compare similar foods or they may be used to compare meals, main dish items, and dissimilar foods within a product category (e.g., potato chips to pretzels) provided that the food for which the claim is made meets the nutrient requirements for the claim (e.g., "less fat," contains at least 25% less fat compared to the reference food) and the food or meal bearing the claim could reasonably be expected to be substituted for the food to which the comparison is made (e.g., one appetizer for another, one entree for another) (21 CFR 101.13(j)(1)(i)(A)).

86. I understand that restaurant labeling that bears a claim must comply with the definition for the claim set out in the claims requirements. Does restaurant labeling also need to comply with the requirements for label statements and accompanying information set out in the claims regulations? For example, if a beverage contains 30 mg of sodium per RACC (8 fl oz (240 milliliters)) it meets the nutrient content criterion for a "very low sodium" claim (i.e., 35 mg or less sodium per RACC). A 12 fl oz serving of the same beverage would contain 45 mg sodium per serving. While the beverage still meets the criterion for a "very low sodium" claim based on the nutrient amount per RACC, it would not meet the criterion based on its serving size. Sections 101.12(g) and 101.13(p)(1) of the claims regulations require that, when labeled serving size is different from the RACC and the food does not meet the nutrient content criterion in the definition for the claim based on labeled serving size, the claim must be followed by a statement providing the criterion for the claim (e.g., "Very low sodium, 35 mg or less sodium per 8 fl oz (240 milliliters)").

Answer: Generally, restaurant labeling must comply with all requirements for a claim unless specifically exempted from the requirement (21 CFR 101.13(q)(5)). Relative claims, for example, must be accompanied by a statement identifying the reference food and the percent (or fraction) of the amount of the nutrient in the reference food by which the labeled food differs (e.g., "Reduced fat cheese cake, contains 25% less fat than regular cheesecake").

However, consistent with the agency's flexible approach to restaurant labeling, FDA would use its regulatory discretion in evaluating labeling that bears a claim but for which compliance with a particular requirement may be difficult or inappropriate (e.g., because of the way in which a food is served (e.g., unpackaged, no labeled serving size or ingredient declaration) or the way the claim is presented (e.g., a single claim in a heading in labeling for a group of foods, or nutrition labeling that is independent of the labeling that bears the claim). While FDA has stated that some information (e.g., the identity of a reference food) is material to consumers' understanding of a claim, the agency would not object, in a restaurant situation, to the required accompanying information being presented in other labeling, (e.g., in a brochure or notebook along with nutrient information), when it is impractical for such information to accompany the claim (e.g., multiple claims on a menu with limited space).

V. EXEMPTIONS AND SPECIAL LABELING PROVISIONS (21 CFR 101.9(j))

Foods Which are Served or Sold in Establishments in Which Foods are Served for Immediate Consumption (21 CFR 101.9(j)(2)):

87. If a restaurant makes a claim for one item, does it need to provide nutrition information for all the foods it serves?

Answer: No. The exemptions in 21 CFR 101.9(j)(2)(i) through (iii) apply to individual food items that are served or sold in a restaurant or similar

establishment, not to the establishment. A restaurant need only provide nutrition information for those items that bear a claim. The restaurant may voluntarily provide nutrition information for restaurant foods that do not bear a claim.

88. Are foods sold to and used by restaurants in food preparation, but not served to consumers in the package in which they are received, exempt from nutrition labeling, even if claims are made?

Answer: Yes. The exemptions in 21 CFR 101.9(j)(2)(iv) for foods sold for use only in restaurants but not served directly to consumers in the package received (e.g., large quantity containers) and in 21 CFR 101.9(j)(2)(v) for foods sold by a distributor who principally sells food to such facilities are not conditional on the absence of claims as are the other exemptions under 21 CFR 101.9(j)(2) because the consumer will not see these package labels. However, manufacturers, packers, or distributors may wish to place nutrition information on the label of the package or case, or in a flyer in each case of product, for the benefit of the food service operator who may need such information to support any claims made to consumers in the restaurant. Likewise, the restaurateur may require nutrient content information as a condition of purchase.

89. How does FDA define "restaurants?"

Answer: The term "restaurant" applies broadly to establishments where food is served or sold for immediate, on-site consumption (e.g., institutional food service establishments, such as schools, hospitals, and cafeterias; transportation carriers, such as trains and airplanes; delicatessens, and catering where there are facilities for immediate consumption on the premises).

The definition of "restaurant" extends to establishments where foods are generally consumed immediately where purchased or while walking away (e.g., lunch wagons, cookie counters in a mall, and vending machines, including similar foods sold from convenience stores); and food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices for immediate consumption.

90. Are all foods that are sold in restaurants or from other facilities such as vending machines and that do not bear a claim exempt from nutrition labeling?

Answer: No. The exemptions in 21 CFR 101.9(j)(2)(i) through (iii) are limited to (1) ready-to-eat foods served in restaurants and in other establishments in which food is sold for immediate human consumption and (2) foods sold for sale or use *only* in such establishments. Commercially packaged foods such as soft drinks in cans, bags of potato chips, and candy bars that may be sold in restaurants and vending machines but that are also sold through other retail outlets (e.g., grocery stores) must bear nutrition labeling, regardless of whether or not they bear a claim (subject, of course, to the low volume product and small business exemptions).

91. Are foods that are served aboard airlines required to have nutrition labeling?

Answer: Food served aboard airplanes and other common carriers is exempt from nutrition labeling under 21 CFR 101.9(j)(2)(ii) provided it does not bear a claim.

92. A restaurant serves a salsa that was commercially manufactured under the restaurant's brand name. The restaurant also offers a bottled salsa for sale to patrons for later use. The food does not bear a claim. To be eligible for an exemption under 21 CFR 101.9(j)(2), does it matter whether the food is served for immediate consumption or whether it is sold in packaged form?

Answer: No. The exemptions in 21 CFR 101.9(j)(2)(i) through (iii) cover foods that are served or sold in restaurants and similar establishments, regardless of whether they are sold in packaged form provided their sale is limited to restaurant establishments. However, FDA strongly encourages that products such as the bottled salsa bear nutrition labeling when they are sufficiently standardized to do so.

93. A bottled salsa sold in a restaurant is also sold through conventional retail outlets. The food does not bear a claim. Must the food bear nutrition labeling?

Answer: Yes. The exemption in 21 CFR 101.9(j)(2)(iii) for foods sold in restaurants specifies that the food be sold only in restaurants. Because the sale of the salsa is not limited to restaurants, both products (i.e., restaurant and retail) must bear nutrition labeling under 21 CFR 101.9. The exceptions to this requirement would be (1) foods that are packaged differently for use in restaurants compared to the food sold at other retail locations (e.g., catsup, soy sauce, and other condiments packed in decorative containers for table service), and (2) products covered by the small business or low volume products exemptions.

94. Would foods sold in a gift shop attached to a restaurant or food items sold from a counter across the aisle from the cash register in a truck stop be considered "restaurant foods?"

Answer: If the retail area is located in close proximity to the restaurant (e.g., across the aisle from the area where food is served), and if it is not operated independently from the restaurant, it could be considered part of the restaurant establishment and the foods sold therein may qualify for the "restaurant food" exemption. However, any food item whose sale is not limited to restaurants would not be a restaurant food and, therefore, would not be eligible for the exemption in 21 CFR 101.9(j)(2)(iii).

95. Could you elaborate on the types of foods sold in vending machines that are exempt from nutrition labeling?

Answer: Foods that are prepared or dispensed by a vending machine (e.g., soda, coffee, soup, or popcorn that is dispensed into a cup) would be analogous to foods served in a restaurant and, therefore, would be exempt from nutrition labeling requirements provided the food does not bear a claim (21 CFR 101.9(j)(2)(ii)).

Vending machine foods sold in packaged form (e.g., a salad or sandwich prepared in a commissary) that are similar to foods sold in restaurants are exempt from nutrition labeling requirements under 21 CFR 101.9(j)(2)(iii) provided the food does not bear a claim and it is not sold through other retail channels (e.g., grocery stores).

The exemption for food sold in restaurants and similar establishments, including vending machines, extends to commercially manufactured foods that have been specially packaged for sale only in such establishments. However, FDA strongly encourages that foods that are sufficiently standardized to bear nutrition labeling (e.g., individual serving size cans of soup) do so.

96. Could you elaborate on the types of foods that are sold from convenience stores but that would be exempt from nutrition labeling because they are similar to restaurant foods?

Answer: FDA has stated that the exemption from nutrition labeling for such foods should be limited in scope and that some enforcement decisions will need to be made on a case-by-case basis. Generally, however, the foods covered by this exemption must be of the type served in restaurants or similar establishments (i.e., ready-to-eat, sold for immediate human consumption). Such foods would be expected to be non-standardized (e.g., prepared in a commissary kitchen similar to a restaurant or cafeteria kitchen where foods are assembled by hand and subject to individual product variations) and to have a short shelf-life.

Examples of such foods would include: sandwiches; single-serving packages of salads, pies, and puddings; and soups and beverages dispensed into cups, that are in direct competition with foods served in restaurants and that are generally consistent with the above criteria.

In contrast, this exemption would not extend to foods that are not ready-to-eat or are not for immediate consumption. As discussed in response to question 107, there is a separate exemption from nutrition labeling for ready-to-eat foods not for immediate consumption (e.g., ready-to-eat foods that are processed or prepared at the location from which they are sold but that are sold for later use (21 CFR 101.9 (j)(3)). Where the food sold in a convenience store is sufficiently standardized to bear nutrition labeling, it should do so, unless otherwise exempt.

97. If an exempt sandwich sold in a vending machine or convenience store includes a single serving unit of a condiment, such as mayonnaise, must nutrition labeling be provided on the mayonnaise packet?

Answer: Foods that are eligible for the exemption from nutrition labeling under 21 CFR 101.9(j)(2), including sandwiches sold from lunch wagons, vending machines, and convenience stores, are exempt in their entirety. Therefore, a mayonnaise packet packaged with a sandwich is also exempt as long as its label does not bear a claim or other nutrition information.

98. Would a single serve package of a condiment be exempt from nutrition labeling if it is served on its own (e.g., placed in a bowl on a table)?

Answer: Yes. Food that is served in a restaurant or similar establishment is exempt from nutrition labeling provided that the food does not bear a claim (21 CFR 101.9(j)(2)(i) and (ii)). Condiments in single serve packages placed in a bowl on a table in a full service restaurant or in a container on a lunch counter or vending facility for consumers to use at their discretion, would be eligible for these exemptions. Likewise, condiments served in larger, multi-serving containers would also be eligible for the exemption under 21 CFR 101.9(j)(2)(i) or (ii) provided the food does not bear a claim.

99. A single-serve package of a condiment is served or sold in restaurants. It is commercially manufactured, packaged, and labeled. The package label bears a claim. How should nutrition labeling be accomplished for the food?

Answer: In the August 18, 1993, technical amendments (58 FR 44020[c2]), FDA amended 21 CFR 101.9(j)(13)(i)(B) to permit individual serving-size packages of food for use in restaurants and similar situations to use the minimum type size allowed under current 21 CFR 101.2(c)(2) of one thirty-second inch for nutrition labeling provided that the packages have a total area available to bear labeling of 3 square inches or less. If, despite this provision, a small package still cannot comply with nutrition labeling requirements, the person responsible for labeling is advised to write the Office of Nutrition, Labeling, and Dietary Supplements, CFSAN, FDA (HFS-800), 5100 Paint Branch Pkwy., College Park, MD 20740 requesting alternative means of compliance in accordance with 21 CFR 101.9(g)(9). (See question 2 and question 3.)

100. A restaurant serves a food that is commercially manufactured, packaged, and labeled. The food is served to consumers in the form it was purchased by the restaurant (e.g., individual serving size packages of condiments are placed in a bowl for consumer use). Would FDA hold the restaurant that serves the food responsible if the label of the food does not meet FDA's requirements, for example, if a package of salad dressing bears a "low fat" claim but fails to bear nutrition information?

Answer: FDA requires that the label of a food sold in packaged form identify conspicuously the name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5). The firm that is so identified is generally the firm that is responsible for insuring that the food is properly labeled.

101. Must a restaurant food be ready-to-eat to be exempt under 21 CFR 101.9(j)(2)?

Answer: Not necessarily. The exemptions for foods served in restaurants and in similar establishments (21 CFR 101.9(j)(2)(i) and (ii)) imply that the food is ready-to-eat and is served for immediate consumption. However, a restaurant may also sell foods for carry-out that are not ready-to-eat (e.g., a pizza that is only half cooked or a pie that is frozen). Further, foods sold for use in restaurants may be used as ingredients in the foods a restaurant prepares but are not, themselves,

ready-to-eat. Thus, the exemptions for foods sold for sale or use only in restaurants (21 CFR 101.9(j)(2)(iii) and (iv)) and for foods sold by a distributor who principally sells food to such facilities (21 CFR 101.9(j)(2)(v)) are not limited to ready-to-eat foods.

102. Company X operates a large chain of restaurants with different facilities and services at each establishment based on the size of the establishment. Larger establishments have facilities for consuming food on the premises, sell food for "carry-out," and offer home delivery services. Some of the company's smaller retail establishments have no on-site eating facilities and all food sold is for "carry-out" or home delivery. Are the foods sold from these establishments exempt from nutrition labeling under 21 CFR 101.9(j)(2)?

Answer: In the above example, all foods served in the larger restaurant establishment would be exempt from nutrition labeling provided the food does not bear a claim. Foods sold for carry-out or home delivery from larger establishments (i.e., establishments with facilities for immediate consumption of the food) would also be exempt provided the food does not bear a claim and sale of the food is limited to restaurant-type establishments.

Foods sold by an establishment with no tables and chairs would still be eligible for the exemption provided that the food is ready-to-eat and is generally consumed immediately where purchased or while walking away (e.g., pizza sold from a walk-up counter in a mall). This exemption extends to foods sold by establishments that have facilities for delivering ready-to-eat foods to homes and offices for immediate consumption. Ready-to-eat "carry-out" foods would be similar to home-delivery foods, with the consumer doing the delivering, provided the foods are sold for immediate consumption.

103. In the preceding example, most of the smaller establishments owned by Company X (i.e., establishments that offer only carry-out and home delivery service) cook, assemble, and otherwise prepare the food on-site. However, a few of the very small locations sell ready-to-eat food for immediate consumption that is prepared at a central commissary and shipped to the retail location. Are these foods still exempt from nutrition labeling under the restaurant food exemption if they do not bear a claim?

Answer: Yes, provided the foods meet the general criteria for restaurant foods (i.e., they are ready-to-eat and sold for immediate consumption). Although foods served or sold in restaurants are frequently prepared on-site, this is not a requirement for this exemption. (There is a separate exemption in 21 CFR 101.9(j)(3) for restaurant-type foods that are ready-to-eat, not for immediate consumption, and prepared at the retail location from which they are sold (see question 107).

104. Would a ready-to-eat food that is normally sold for immediate consumption by a small carry-out restaurant lose its exemption from nutrition labeling if consumers occasionally purchase the food for later use? For example, if a consumer purchases an extra pizza at lunch-time and takes it home for dinner that night or the next day.

Answer: If a food is consistent with the general requirements for the exemption for restaurant foods, it would not automatically lose its exemption because of a limited number of sales that are different from normal practice. When determining whether a food qualifies for an exemption from nutrition labeling, and which exemption applies, FDA would consider how the food would most often be reasonably expected to be sold (e.g., for immediate consumption).

105. Do restaurant foods that make claims need to comply with the same requirements as foods from other sources?

Answer: Restaurant foods that bear a claim must comply with the same definitions for nutrient content claims or qualify to bear health claims under the same authorizing regulations as foods from other sources. At the same time, FDA is providing a measure of flexibility in how restaurateurs determine the nutrient content of their food (e.g., "reasonable basis" for believing a food meets the definition of a claim), and how they communicate this information to consumers (e.g., in a brochure or notebook) (21 CFR 101.10). These provisions are discussed in section IV of this document.

106. Can a State require restaurant foods to bear nutrition labeling even if the food is exempt under Federal requirements?

Answer: Yes. Even though claims on menus are not currently subject to NLEA, States would be free to apply nutrition labeling and claims requirements to claims on menus. Furthermore, because the FD&C Act exempts restaurant foods that do not bear a claim from mandatory nutrition labeling, State requirements for the nutrition labeling of such foods would not be preempted. The FD&C Act also exempts restaurant foods that bear a claim from certain disclosure statements. Thus, State requirements of this type would not be preempted (FD&C Act section 403A(a)).

The NLEA provided for Federal preemption of State and local requirements that are not identical to the Federal requirement in a number of key areas of food labeling (section 403A (a) of the FD&C Act). However, sections 403A(a)(4) and (5) of the FD&C Act provide that State requirements of the type required by 403 (q) (nutrition labeling) and 403(r)(1) (claims) would not be preempted for foods that are exempt from the Federal requirements.

Ready-to-Eat Foods Not for Immediate Consumption (21 CFR 101.9(j)(3)):

107. I own a "gourmet-take-away" store. Many of the items sold in the store are ready-to-eat, similar to foods served in restaurants. However, the foods are not usually purchased for immediate consumption. Must these foods bear nutrition labeling?

Answer: It depends. 21 CFR 101.9(j)(3) exempts the types of ready-to-eat foods that would have been exempted by 21 CFR 101.9(j)(2)(i) or (ii) (i.e., ready-to-eat foods that are served in restaurants and similar establishments and that do not bear a claim) had it not been for the requirement that the food be sold in an

establishment that has facilities for immediate consumption.

To be eligible for the exemption in 21 CFR 101.9(j)(3), restaurant-type foods that are sold by retail establishments that do not have facilities for immediate consumption must be: (1) similar to foods served in restaurants, (2) ready-to-eat, (3) primarily processed or prepared at the retail establishment from which they are sold, and (4) not offered for sale outside such establishment.

Accordingly, ready-to-eat food that is prepared on-site, and that is sold only from such retail location, is exempt from nutrition labeling under 21 CFR 101.9(j)(3) provided that it does not bear a claim, regardless of whether or not there are facilities for on-site consumption. Foods that are prepared elsewhere but are portioned and packaged to consumer specifications at retail would fulfill the prepared on-site criterion.

108. To be exempt from nutrition labeling under 21 CFR 101.9(j)(3), foods must be ready-to-eat. Are cold entrees, such as lasagna or pizza, considered ready-to-eat even though they are generally eaten hot?

Answer: As long as the food is fully cooked, it is considered ready-to-eat. For example, a pizza with a raw crust that requires cooking before consumption would not be "ready-to-eat." However, a pizza that is cooked and then cooled would be. While most customers would be expected to reheat the food before consumption, it would not be necessary that they do so.

109. Could you elaborate on which foods sold from delis and bakeries that do not have facilities for immediate consumption of food (including independent deli's and bakeries and the deli or bakery cases of retail stores) are exempt from nutrition labeling under 21 CFR 101.9(j)(3)?

Answer: Foods sold from behind deli and bakery service cases, where the customer must make a selection and indicate the amount of the item desired, are exempt unless the food bears a claim or other nutrition information. When claims or other nutrition information are given, nutrition labeling needs to be displayed clearly at the point-of-purchase. When the deli or bakery foods that are regulated by FDA are packaged for self-service, they are only exempt from nutrition labeling if the product was primarily processed or prepared on-site, and no claims are made for the product.

If the food is primarily processed or prepared on the premises from which it is sold, it is exempt from nutrition labeling, regardless of how it is sold (i.e., from behind the counter or pre-portioned packages from a self-service shelf).

110. Would bread baked at the retail location qualify as "primarily processed or prepared on-site," if the bakery is using dough that was pre-formed at a different location? What if the bakery adds icing to a cake that was baked elsewhere?

Answer: To meet the criterion for being "primarily processed or prepared on-

site," the food must be augmented on site in a manner that changes the nutritional profile of the food, i.e., filling, icing, enrobing. Foods that are assembled on-site meet this criterion even though some components of the food (e.g., the bread or cheese used in a sandwich) were prepared elsewhere. Similarly, cakes that are custom decorated at the retail location are exempt, even if the cake was baked elsewhere. Garnishing (e.g., adding sesame seeds to bread dough) would fall under the definition of "primarily processed or prepared on-site" if the added food changes the nutritional profile of the finished product. In contrast, if a food is merely portioned on-site or if pre-formed dough or pre-scaled/-molded dough is simply thawed or merely proofed and baked at the retail location, the product is not "primarily processed or prepared on-site," and nutrition labeling is required.

111. Is nutrition labeling required for orange juice that is freshly squeezed in the produce section of the retail store?

Answer: No, this product is produced on the premises from raw oranges available in the retail section of the store. It may be collected in containers brought in by consumers or containers available from the retail store. The product need not have nutrition labeling.

112. Must cheeses that are cut into slices or wedges and packaged in retail establishments bear nutrition labeling?

Answer: Cheese is generally not processed or prepared on the premises. Therefore, unless it is sold from behind the deli counter (i.e., portioned to consumer specifications), it would not qualify for an exemption under 21 CFR 101.9(j)(3). When pre-portioned, wrapped, and put out on a self-service counter, it is a packaged food and must meet all labeling requirements.

113. Must slices of cheesecake that are cut and packaged in retail establishments bear nutrition labeling?

Answer: If the cheesecake is primarily processed or prepared on the premises, or if it is sold from behind the deli counter, it is exempt under 21 CFR 101.9(j)(3). If it does not meet either of these criteria, it must bear full labeling. As with cheese, when pre-portioned, wrapped, and put out on a self-service counter, it is a packaged food and must meet all labeling requirements.

114. A deli purchases 6 and 8 lb loaves of bread that it cuts and sells by unsliced, random weight portions. Is nutrition labeling required for the bread, and if so, how can the deli declare "Serving size" and "Servings per container" for the unsliced, random weight portions?

Answer: Nutrition labeling would be required on the cut pieces when they are packaged and put out on a self-service shelf, or if claims are made on the product when sold from behind the counter. When labeling is required, the serving size for the unsliced bread should be based on the RACC (e.g., "2 oz (56 g/1 inch slice)"), and the "Servings per container" could say "varied," so that the same nutrition

label could be used on all random weight portions.

115. Is nutrition labeling required for foods sold in a salad or soup bar in a retail store?

Answer: Unpackaged ready-to-eat foods available for self-service from salad and soup bars in a retail store (i.e., a grocery store that does not have facilities for immediate consumption) are generally exempt under 21 CFR 101.9(j)(3) since the foods are of the type often sold from a service counter or deli case and are portioned to consumer specifications (even though it is the customer, not store personnel, who is portioning the food item). This exemption includes ready-to-eat food, not for immediate consumption, that is primarily processed or prepared at the retail location from which it is sold, regardless of whether it is sold wrapped or self-service.

If the food is ready-to-eat and is sold for immediate consumption, it may also qualify for the restaurant food exemption, even if it is sold from a retail establishment with no facilities for immediate consumption. (See, e.g., foods sold in convenience stores that are in direct competition with restaurant foods (question 89).

The above exemptions are dependent on the food not bearing a claim or other nutrition information. If a claim is made (e.g., "low fat pasta salad"), or when other nutrition information is provided, the above exemptions are lost, and nutrition information must be provided.

116. When party platters of vegetables and dip or cheeses are made up in the deli or produce section of a retail store, must the platters bear nutrition labeling? On vegetable platters, does it make a difference if the dip is prepared in the store or is a commercially prepared product?

Answer: Platters prepared or assembled at a retail location and sold from such retail location are exempt under 21 CFR 101.9(j)(3), regardless of whether the platter includes a commercially processed food component, such as a dip. In contrast, platters that are prepared in a central commissary and shipped to the retail store must bear nutrition labeling (except platters containing only fresh fruits or vegetables that are exempt under the voluntary nutrition labeling program 21 CFR 101.9(j)(10)).

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(1) This guidance has been prepared by the Office of Nutrition, Labeling, and Dietary Supplements in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

FDA/Center for Food Safety & Applied Nutrition
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